Program Description
Animal Care and Use Program

Oakland University

001294

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For
AAALAC International

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Program Description

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

Section 1. Introduction

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

The Biomedical Research Support Facility (BRSF) and its staff provide veterinary and technical assistance, animal husbandry, facility management, acquisition and procurement of research animals, and surgical and post-operative support for animal related research. *Institution,* includes all the constituent units of Oakland University: the College of Arts and Sciences and all Schools, Institutes and Centers.

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.

In keeping with Oakland University's mission statement, to advance knowledge and promote the arts through research, scholarship, and creative activity, Oakland University assumes an obligation to advance knowledge through the research and scholarship of its faculty and students. The university's research and scholarship mission takes expression in a variety of forms ranging from basic studies on the nature of things to applied research directed at particular problems to contributions to literature and the arts. Within its means, the university provides internal financial support for research and scholarship. Simultaneously, it pursues with vigor external sources of support. Research institutes, financed primarily by outside grants, make an important contribution to this mission. The university further recognizes that scientific and medical knowledge developed through animal research has saved countless lives, has improved human and animal health, and has alleviated pain and suffering. Oakland University supports judicious use of animals in research, education, and testing, in the interests of human and animal welfare, thus ensuring that animals are not used needlessly and are spared unnecessary pain and distress. In recognizing its legal and ethical responsibilities, Oakland University's program fosters the humane care and use of animals and adheres to all applicable federal, state, local, and institutional laws or guidelines governing animal research, regardless of the sources of support. To this end, Oakland University has maintained a university-wide Animal Care and Use Program, which is overseen by Institutional Official, the Attending Veterinarian, the Institutional Animal Care and

Use Committee (IACUC), and implemented through the Biomedical Research Support Facility.

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.

Oakland University's Institutional Animal Care and Use Program employs the standards of the 8th Edition of the Guide for the Care and Use of Laboratory Animals (Guide), NRC 2011, and the Office of Laboratory Animal Welfare (OLAW) Public Health Service (PHS) Policy for all animals. The standards of the U.S. Department of Agriculture (USDA) Animal Welfare Act Regulations are applied for all covered species. The Guidelines for Use of Fish in Field Research by the American Fisheries Society is used for fish field research, and the Guidelines for Use of Live Amphibians and Reptiles in Field Research compiled by the American Society of Ichthyologists and Herpetologists, the Herpetologists' League, and the Society for the Study of Amphibians and Reptiles, is used for amphibian field research.

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

the Attending Veterinarian, and the Institutional Official.

The responsibility for implementing the program is assigned to the Research Office, subject to periodic review and approval of the implementation procedures by Oakland University's Institutional Animal Care and Use Committee (IACUC), and the Associate Vice President for Research (AVPR), who serves as Institutional Official (IO) to the United States Public Health Service (PHS) and the United States Department of Agriculture (USDA).
The Institutional Official (IO), the Attending Veterinarian (AV), the IACUC and the IACUC Chair, the Director of Regulatory Support, and the BRSF Animal Research Facility Manager work together to oversee the Animal Care and Use Program and to resolve any issues. The BRSF also employs one full-time facility Coordinator, and four casual Research Laboratory Veterinary Technicians. IACUC appointments are made by the President of the university at the recommendation of the AVPR. Current IACUC members, the BRSF Manager, the Director of Regulatory Support or others may advise the AVPR on the appointment of new committee members as needed.

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.

Ora Hirsch Pescovitz, MD, President and Chief Executive Officer
James P. Lentini, PhD, Senior Vice President for Academic Affairs and Provost
David A. Stone, PhD, is the Associate Vice President for Research and the Institutional Official
Keith Williams, PhD, is the chairman of the Institutional Animal Care and Use Committee
Lori Penman, DVM, is the Attending Veterinarian
Rebecca Sandborg, PhD, is the Director of Regulatory Support
Janet R. Schofding, AS, BS, LVT, RLATG, is the manager of the core animal research facility known as the Biomedical Research Support Facility (BRSF) and the IACUC Administrator
Domenico Luongo is the Laboratory Compliance Manager with the Office of Environmental Health & Safety (EH&S) and provides biosafety, chemical hazard and radiation oversight

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

The BRSF and its staff provide experimental animals and research support to an average of 18 principal investigators a year. Currently, 41 IACUC approved protocols encompass the areas of biological field studies, animal behavior studies, ophthalmic medicine, neuroprotection and neurogenesis, eye research, retinal gene expression, cell biology, genetic mapping, thrombosis hypertension and pharmacological studies.

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

The sources of annual research funding involving the use of animals include Internal funding opportunities through the Institute for Stem Cell and Regenerative Medicine (ISCRM), and University Research Committee (URC) Faculty Research Fellowship, and the Center for Biomedical Research (CBR): External federal funding through the National Institutes of Health (NIH), National Science Foundation (NSF), National Eye Institute (NEI), American Heart Association (AHA), Retinopathy of Prematurity and Related Diseases (ROPARD) & Retinal Solutions LLC, the Pediatric Retinal Research Lab, and the Michigan Departments of Environmental Quality and Natural Resources.

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.

There are none.

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.

There are none.

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

There are no minority views or unresolved issues as identified in the IACUC minutes and/or semi-annual reviews.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

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

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

The primary oversight responsibilities of Oakland University's Animal Care and Use Program rest with the Institutional Official, the Attending Veterinarian, and the IACUC. Together they establish policies and procedures, ensure regulatory compliance, monitor the performance of the program, and support quality research, and humane animal use. The Institutional Official is notified in advance of all IACUC meetings and receives copies of the minutes of all convened meetings. The IACUC, of which the Attending Veterinarian is a member, meets monthly for full committee meetings and conducts special meetings as determined necessary by the IACUC Chair. Additionally, a sub-committee of the IACUC meets every six months to conduct Semiannual Program Reviews and Facility Inspections, following the 8th Edition of the Guide for the Care and Use of Laboratory Animals established by the National Research Council (NRC), and the PHS Policy on the Humane Care and Use of Laboratory Animals as described in Oakland University's OLAW Assurance. Semiannual Reports of these reviews and inspections address any concerns involving the care and use of animals at the institution. These reports are submitted to the Institutional Official with recommendations and specific plans and timelines to address any deficiencies cited. The Institutional Official, the Attending Veterinarian, the IACUC, the Director of Regulatory Support, and the BRSF Animal Research Facility Manager work together to oversee the Animal Care and Use Program and to resolve any issues. The Director of Regulatory Support serves as a liaison between the IO and the university regulatory committees, such as the IRB, the IACUC, and the IBC. The Institutional Official has the authority to allocate resources needed to ensure the Program's overall effectiveness.

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.

Lori Penman, D.V.M., is the Attending Veterinarian responsible for providing veterinary care for all research animals under Oakland University's jurisdiction. Dr. Penman provides veterinary services both remotely and on-site. She has served in this capacity since July, 1991. Dr. Penman is on-site for IACUC meetings, Semiannual Program Reviews and Inspections of Facilities, and as needed for veterinary care, averaging approximately once visit per month. She provides on call service 24 hours a day, seven days a week, except when prior arrangements are made for emergency back-up veterinary care. During regularly scheduled visits, she tours the facility, inspects the animals and evaluates their health status and care needs and meets with the staff for open discussions. Duration of the visit is determined by the needs identified during the walk-through of the facility.

The Attending Veterinarian is responsible for the well-being and clinical care of animals used in research, testing, teaching, and production. This responsibility extends to monitoring and promoting animal well-being at all times during animal use, and during all phases of the animal's life. The Attending Veterinarian upholds the highest standards of care and ethics. The Institution, the IO, and the IACUC, have granted the Attending Veterinarian sufficient authority and resources to manage the program of veterinary care: to have access to all animals, to treat an animal and institute appropriate measures to relieve severe pain or distress, to remove them from the experiment, or perform euthanasia. In fulfilling these duties in the research environment, the Attending Veterinarian interacts collaboratively with the research team (e.g., the Principal Investigator) when making critical decisions regarding animal health and welfare. Important aspects of the role of the Attending Veterinarian and the program of veterinary care include, but are not limited, to the following:

- Serves on the IACUC.
- Provides clinical and/or program oversight and support with the expertise necessary to appropriately evaluate the health and well-being of the species used, in the context of the animal use being carried out by the institution.
- Provision of veterinary medical care, and emergency veterinary care is available at all times, including after work hours, on weekends, and on holidays.

- Has oversight of additional aspects of the veterinary care program, such as preventative medicine and health surveillance, medical treatment, establishment of sedation, anesthetic and analgesic guidelines, handling, and immobilization, and has oversight of other related aspects such as housing and husbandry.
- Provides guidance and oversight to surgery programs and perioperative care.
- Provides veterinary care and consultation as needed for general medical care and on the recognition and palliation of pain.
- Reviews protocols and makes recommendations to the IACUC regarding animal welfare issues related to proposed research activities, the development of study removal criteria, and responsible conduct of research activities.
- Consults with researchers and the IACUC to provide information about alternative procedures to reduce pain and distress. Advises the IACUC on new procedures that will help to reduce or eliminate the potential to cause pain and distress.
- Serves as a resource for IACUC members, PIs, graduate students on issues related to animal welfare.
- Providing expertise on matters of animal health and welfare, including, but not limited to: use of proper anesthesia and analgesia in laboratory animals in the relief of pain and distress; discussion of the possible complications related to procedures used or a disease model proposed; provide a review of the plans for appropriate and timely medical intervention.
- Authorizing a halt to any animal activities in question until an investigation can be performed.
- Authorizing euthanasia for any animal in pain or distress that cannot be otherwise alleviated.
- Requiring humane use of the animals while ensuring the scientific requirements of the study are met.
- Understands the potential for adverse clinical complications that may arise from experimental procedures.
- Assisting with training and education of IACUC members, PIs, students, etc. as needed. In association with the IACUC, has the responsibility for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures to be performed.
- Participate in semi-annual facility inspections and program reviews.
- Reviews IACUC Policies and Procedures, PHS OLAW Assurance, and other documents as needed that are related to regulatory compliance.
- Providing emergency services as required.
- Remains knowledgeable about the latest practices and procedures to ensure that high quality care is provided to animals.

The AV maintains regular and clear communications with the IACUC Chair and the Animal Research Facility Manager/IACUC Administrator in order

for animal program needs to be regularly and clearly communicated to the IO.

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.

BRSF staff are designated to be responsible for daily animal care and use and facility management.

The BRSF staff, comprised of the Animal Research Facility Manager, the Facility Coordinator, and two part-time Research Laboratory Veterinary Technicians, and one Research Laboratory Assistant which is a student position, provide veterinary and husbandry care as directed by the Attending Veterinarian: Pre-operative, intra and post-operative care, daily monitoring of animals' health, treatments and physical exams as needed, and close monitoring of animal protocol compliance. The Animal Research Facility Manager, and two of the Research Laboratory Veterinary Technicians, are licensed LVTs with the State of Michigan and are on site, or on call, every day of the year and are authorized and capable of providing medical treatments at the direction of the Attending Veterinarian.

Principal Investigators, their staff, and project personnel participating in IACUC approved projects and involved with performing specific procedures on research animals have all been appropriately trained and are qualified to perform their respective duties properly. These individuals report to the AV directly or through BRSF staff.

Anne Fitzgerald, D.V.M., DACLAM, a veterinarian with specific training and experience in laboratory animal medicine, provides emergency veterinary care by specific arrangement when the Attending Veterinarian is unavailable.

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.

The NIH Office of Laboratory Animal Welfare (OLAW) has clarified the roles that Oakland University may assume when participating with other institutions

in PHS-assured collaborative research. Oakland University's collaborative activities are beneficial to successful research endeavors.

Oakland University assures all research is conducted in an appropriate and legal manner when collaborating with other institutions. Oakland University's Institutional Animal Care and Use Committee (IACUC) serves as the coordinator for the Animal Care and Use Program. When OU collaborates with other institutions, the IACUC of record will be determined on a case by case basis taking into consideration where animal activities will be conducted, ownership of the animals and federal funding sources. The OU IACUC may defer local oversight of animal activities to another institution's IACUC and maintain a record for the basis of such decisions.

The IACUC works closely with the Research Office in order to assure that all necessary requirements have been met prior to the IACUC authorizing animal care or use in a collaborative arrangement.

Memorandums of Understanding (MOU) with the collaborating institutions are established to identify the responsibilities/obligations of each institution in regards to animal care and use. The collaborator understands and acknowledges its responsibilities under these agreements to comply with Oakland University's institutional policies, applicable federal, state, and local laws and regulations, ethical guidelines, and other policies and principles as covered in the MOU. In addition, when federally funded, the MOUs address the negotiated scientific, administrative, financial, and reporting requirements of the grant. This written agreement also includes the incorporation of applicable public policy requirements, including agreement for meeting the PHS Policy requirement for review and approval of proposed animal activities, and significant changes to animal activities.

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.

Oakland University's Institutional Animal Care and Use Committee (IACUC) initiated a program of training called the Collaborative Institutional Training Initiative Program (CITI Program). CITI Program is a web-based subscription service providing research ethics education to all members of the research community. BRSF staff, Principal Investigators with currently approved IACUC protocols, and any personnel listed on those protocols, and all new approved

personnel are required to take specific IACUC required CITI Program Training courses prior to the start of their research projects. Each individual is required to complete the training once, with a refresher course being required every three years thereafter. Copies of Course Completion Reports are emailed to the IACUC's CITI Program Administrator for verification of training. These completion reports are kept on file on the CITI Program website and can be accessed at any time by the CITI Program Administrator for verification purposes.

All employees participate in other on-line, annual*, mandatory training specific to their duties. The on-line training includes the following modules:
General Lab Safety (Right to Know)
Bio-safety
Bloodborne Pathogen Exposure Control*
Radiation Safety*
Radiation Awareness Training
Analytical X-Ray and Radiation Producing Machines Safety
Laser Safety
Robotics Safety
Hazardous Materials and Waste Management
Shipment of Biological and Hazardous Materials
Laboratory Lock Out/Tag Out
In order to measure and ascertain the effectiveness of the training, all personnel are subject to observation by the Attending Veterinarian and/or BRSF staff at any time that animal handling or procedures are being performed. In addition, BRSF staff conduct post-approval monitoring and auditing of all ongoing research that occurs on a daily basis in the facility.

New hires attend a central, institution-wide "Right to Know" training and a department specific "Right to Know" in-service, consistent with the Hazardous Materials and Waste Management training. Safety Data Sheets (SDS) are available in hardcopy on-site in the facility. The Radiation Safety Officer provides a radiation safety in-service to staff working with radiation and monitors radiation badge use per the Radiation Safety Manual policies.

BRSF staff, and principal investigators and their personnel are provided with the Training and Information Manual for Animal Care and Use. The manual contains information regarding the Occupational Health Program for Animal Colony Personnel which addresses the area of Zoonotic Diseases. New protocols or procedures identified as potential safety risks are addressed as they arise. On-site training and communication related to Occupational Health and Safety for BRSF staff is administered by the BRSF manager. Project-based training is managed as previously described.

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.

Lori Penman, D.V.M. – Attending Veterinarian
Full Time Work Experience: Private Practice 6 yrs; Lab Animal Medicine 16 yrs; Industry 17 yrs; Total Lab Animal Experience 27 yrs.
Assistant Director - AAALAC accredited facility 9 yrs;
Oakland University - Attending Veterinarian 26 yrs;
Memberships: MALAM - (Michigan Academy of Laboratory Animal Medicine), Past President, 1993
MVMA (Michigan Veterinary Medical Association)
Board of Directors - MALAM representative, 1994-1999
Current MALAM, representing Lab Animal
Chairman or Member, Animal Welfare Committee - 2000 - Present
AAIV (American Association Industry Veterinarians), Member 2006 - Present
AVMA (American Veterinary Medical Association) Member, 1984 – Present
Continuing education includes attending veterinary professional conferences, lectures and webinars. Mandatory Continuing Medical Education is now the law in Michigan. Every three years, 45 hours of approved continuing education credits needs to be completed.

Janet R. Schofding, A.S., B.S., LVT, RLATG – Manager, Biomedical Research Support Facility-Animal Research Facility
In 1994, she earned her certification as a Laboratory Animal Technologist (LATG) through the American Association for Laboratory Animal Science (AALAS). She is recognized as a Registered Laboratory Animal Technologist (RLATG) through AALAS. As a requirement to uphold her RLATG status, she is required to complete 24 continuing education credits (CEU) every two years. She earned her bachelor's degree from Wayne State University. She is certified in Basic Microsurgery through Providence Hospital. Janet began her career working for the Humane Society of Macomb. She went on to work with the Birmingham, Michigan Police Department with their Animal Control Unit. Janet spent 5 years working for private practice veterinary hospitals. She has 30 years of experience in laboratory animal science, with 14 years at Wayne State University working for the Department of Surgical Research Services, and 16 years at Oakland University. Janet is also the Administrator for the IACUC ,and the Administrator of CITI Program Training. Janet maintains membership in;

the Michigan Branch of the American Association for Laboratory Animal Science (MI-AALAS), the Michigan Association of Veterinary Technicians (MAVT), the Michigan Society for Medical Research (MISMR). Her education has continued throughout her career. She has attended numerous local, regional, and national laboratory animal conferences, meetings, and seminars. Mandatory Continuing Medical Education is now the law in Michigan. Every three years, 15 hours of approved continuing education credits needs to be completed.

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

1) Indicate the number of animal care personnel.

Two Full-Time Staff: Animal Research Facility Manager and the BRSF Coordinator
Two Part-time Staff: Research Laboratory Veterinary Technicians
One Student Position: Research Laboratory Assistant

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.

Clifford Snitgen, LATG – holds the full-time position as the BRSF Coordinator. He has been a member of Michigan AALAS since 1984, and a member of National AALAS since 1979. He received his AALAS certification as a Laboratory Animal Technologist (LATG) in 1987. In addition to earning approximately 60 undergraduate credit hours at Wayne State and Oakland University, Cliff has attended numerous workshops, training sessions and courses, offered through AALAS and Oakland University that deal with professional management and development. He continues to participate in numerous continuing education opportunities.

Barbara Barber, B.A., M.S. – earned her Bachelor of Fine Art in Graphic Design, and a Bachelor of Art in Photography from Michigan State University. She earned her M.S. in Historic Preservation from Eastern Michigan University. She has experience working for a private veterinary hospital, is a MSU Extension 4-H Member, and has worked with Michigan Wildlife Rehabilitators. She has also completed training and has experience working with Wild Animal Care and Rehabilitation Environmental Education and USA Grant Writing. She is active in working for Historic Preservation and Planning. She has been employed at the BRSF for over five years in the capacity of Research Laboratory Veterinary Technician.

She has received in-house training covering routine animal and facility care, animal handling, and recognition of abnormalities that may occur in laboratory animals.

Mary Miceli, A.S., B.S., LVT, LMT – is a Licensed Veterinary Technician and Licensed Massage Therapist with the State of Michigan. Mary has an Associate's degree in Animal Health Technology from Wayne County Community College and a Bachelor's degree with concentrations in biology and environmental studies from Oakland University. She has worked in a myriad of animal care and wildlife field research settings. Mary has taken additional training in the rehabilitation of oiled Sea Otters and other marine wildlife. Her fieldwork experiences include observation and data collection of the activities of Bald Eagles, Harbor Seals, Orca and Beluga whales in relation to their exposures to oil spills, environmental contamination, habitat changes/loss. Mary is a former animal control officer (peace officer) once responsible for triaging injured animals, facility inspections (e.g. sled dog kennels), and investigating animal cruelty cases. She has attended continuing education relating to LVTs in the veterinary practice, wildlife work, and integrative veterinary medicine.

Amber Spencer, A.S. – is a senior at Oakland University in the Bachelor of Science in Biology program. She has an Associates in Applied Science degree from Oakland Community College. She has worked in one of Oakland University's research labs since January 2017, where she conducts research regarding corneal injury and healing using rats. She has worked at Oakland University's Biomedical Research Support Facility since May 2017 in the capacity of Research Lab Assistant. She has received in-house training covering routine animal and facility care, animal handling, and recognition of abnormalities that may occur in laboratory animals.

All staff are encouraged to attend and participate in local and national laboratory animal science meetings and in other relevant professional organizations. These may include, but are not limited to; forums presented by Michigan Society for Medical Research (MISMR) that promote understanding of biomedical research and testing, including the appropriate use of animals, and annual conferences hosted by the Michigan Association of Veterinary Technicians (MAVT). On-the-job training is supplemented with institution-sponsored discussion and training programs and reference materials that apply to their jobs and the species under their care. Oakland University, through its University Human Resources department, sponsors and affords access to non-animal related courses and professional development series lectures

and classes, for all employees of the university. Skillsoft Curriculum offers an online library of over 1500 courses that provide staff with a vehicle to build and enhance skills and knowledge in personal and professional development.

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.

Principal Investigators are required to identify the procedures that they and all project personnel will be performing and the species that they will be working with. Verification of their experience with the species and procedural techniques are documented in their research application and serve as the basis for CITI training and any additional training the IACUC may require. Oversight is accomplished by the AV and BRSF staff to ensure that research personnel demonstrate the necessary knowledge and skill sets when performing procedures.

Oakland University's Institutional Animal Care and Use Committee (IACUC) initiated the use of the program of training called Collaborative Institutional Training Initiative Program (CITI Program). CITI Program is a web-based subscription service providing research ethics education to all members of the research community. BRSF staff, Principal Investigators with currently approved IACUC protocols, and any personnel listed on those protocols, and all new approved personnel are required to take specific IACUC required CITI Training courses prior to the start of their research projects. All laboratory personnel must complete the appropriate training before working on an animal protocol. Each individual is required to complete the training once, with a refresher course being required every three years thereafter. Copies of Course Completion Reports are emailed to the IACUC's CITI Program Administrator for verification of training. These completion reports are kept on file on the CITI Program website and can be accessed at any time by the CITI Program Administrator for verification purposes.

The IACUC's form, "Application for Use of Vertebrate Animals in Research, Teaching Or Testing" (AUVA), requires the signatures of each principal investigator and department chairperson, declaring their assurance that the research will be conducted in compliance with all applicable policies and procedures regarding the care and use of research animals at Oakland University. Their signatures also assure

that the project will be carried out in a humane and scientific manner, in accordance with the PHS Policy and Animal Welfare Act Regulations.

The Oakland University Training and Information Manual for Animal Care and Use is provided to newly hired staff and used as a reference for continuing education for all staff members and research personnel. This manual is a handbook providing instruction in the humane care and use of animals and can be obtained online by accessing Oakland University's Research webpage. Additional species-specific hands-on training may be required for any research personnel handling animals. Specialized training can be arranged for those individuals requiring it by contacting the BRSF Manager. The BRSF Manager and veterinary technicians continually monitor and advise each investigator throughout the project. The manager and veterinary technicians deal with difficulties or questions as they arise.

a) Briefly describe the content of any required training.

Federal regulations require that all personnel involved in animal care and use be adequately trained to perform their duties, and it is the responsibility of the Principal Investigator to insure that this training takes place. Oakland University's training program for personnel working with animals consists of three parts:

(1) Specific, project related training provided by the principal investigator.

(2) Completion of IACUC required Collaborative Institutional Training Initiative (CITI) Program Training courses. Collaborative Institutional Training Initiative (CITI) Program consolidated three previously required courses into one course specifically designed for Oakland University called, "Working with Animals in Biomedical Research - Basic Course". This newly developed course incorporates all of the content found in the three CITI Program courses entitled, "Working with the IACUC - Basic Course for Investigators, Staff, and Students", "Minimizing Pain and Distress", and "Aseptic Surgery". In addition to this, the following CITI courses are also required: All species-specific courses for species used in the IACUC approved protocol, and the course titled, "Working with Animals in Biomedical Research – Refresher Course (To be completed every 3 years).
IACUC members are required to complete the course, "Essentials for IACUC Members – IACUC Chairs, Members, and Coordinators. CITI training is valid for three years.

(3) Completion of the Office of Environmental Health and Safety's (EH&S) courses:

- Research Hazards Awareness Training - This is a mandatory course for individuals working with laboratory animals or frequenting an area where laboratory animals are used. This course provides details on Oakland University's Occupational Health Program for Animal Handlers. Trainees are provided a general overview of the potential hazards encountered when working with lab animals including zoonoses and animal allergy. This course also provides a comprehensive review of Oakland University's Medical Surveillance program for animal allergy management.
- Laboratory Safety Training - This course is required for all Oakland University personnel and students that work in or around the laboratories where hazardous work may be performed, and/or where hazardous materials are handled or stored. The course details Oakland University's Chemical Hygiene Plan and includes instructions and training in safe standard laboratory work practices, use of personal protective equipment, health and safety information for chemical hazard classes, Safety Data Sheets (SDS), and toxicology overview. Training also reviews emergency preparedness and response procedures.
- If the IACUC protocol has a corresponding Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC), or an Institutional Review Board (IRB) application, then any required training associated with those applications needs to be completed also.

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

All required training must be completed before an individual is allowed to work on an IACUC approved protocol. BRSF staff, Principal Investigators with currently approved IACUC protocols, and any personnel listed on those protocols, and all new approved personnel are required to take specific IACUC required CITI Program training and EH&S courses prior to the start of their research projects. Personnel added to a protocol post-approval, are required to complete all required training courses before they are approved to work on the protocol.

c) Describe continuing education opportunities offered.

A refresher course is offered through CITI Program every three years to all individuals who have completed initial course completion requirements. The Oakland University Training and Information Manual for Animal Care and Use is provided to be used as a reference for continuing education for all staff members, and

research personnel. Hands on, species-specific training is provided by the ARF manager, BRSF personnel, or the Attending Veterinarian, whenever a new species is brought into the facility, or when additional training is requested by principal investigators and research staff. Oakland University, through its University Human Resources department, does provide non-animal related courses and professional development series lectures and classes, for all employees of the university. In addition, BRSF staff and IACUC members are given the opportunity to attend the Michigan Society for Medical Research (MISMR) Annual Meeting and Symposium. IACUC members and staff are advised and encouraged to attend local seminars and courses involving IACUC topics and issues, animal welfare, animal medicine, etc. Regular professional development and continuing education opportunities help to ensure both that professional staff are knowledgeable about the latest practices and procedures and that the laboratory animals receive high-quality care.

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]

Any initial surgical arrangements are described in the animal research protocol application, including items such as special equipment or supplies, and special requirements for pre- and post-operative care. The IACUC requires that the Principal Investigator consult with the Attending Veterinarian prior to committee review for any protocol with animals in pain category D and/or E. The Principal Investigator would then be asked to meet with the assigned technician to discuss the specifics of their project such as preparation of the animal, requested instruments and/or procedures, necessary drugs, and pre- and post-operative care, etc.

Appropriate species-specific training and CITI Program training is required of all personnel listed on the animal protocol and must be approved by the IACUC. A licensed veterinary technician would be present at the time that all initial surgeries would be performed. Due to their professional training and experience they can assist in surgery or offer suggestions to improve aseptic or surgical technique. If specific training is required the Attending Veterinarian is available to provide one-on-one training with members of the research/surgical team. The Attending Veterinarian may choose to be present for an initial

procedure, if deemed appropriate in the pre-surgical consultation. Surgical outcomes and adherence to appropriate procedures during all phases of the protocols involving surgery are continually assessed by the BRSF manager and staff, and research personnel, to make certain that procedures are followed and that the well-being of the animals is not compromised. The Attending Veterinarian is kept informed of all findings to ensure that timely corrective changes, if needed, are instituted. Any adverse complications are reported to the IACUC either at the time of incident, and in the Principal Investigator's Annual Protocol Review.

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

All animals in the facility are monitored while under the influence of the anesthetic. Those performing anesthesia are either trained BRSF staff, the Attending Veterinarian, the Principal Investigator, or their research personnel, who have demonstrated via training and experience, their competence in the administration and assessment of analgesia and anesthesia in animals. Appropriate training and experience with the proposed animal species, and a description of the methods used to perform anesthesia is required in the animal protocol and must be approved by the IACUC. The licensed veterinary technicians are trained and competent in all areas of anesthesia. A licensed veterinary technician is present when anesthesia is initially performed by research personnel to ensure that the procedure and technique are being performed correctly and in keeping with the protocol, and that the well-being of the animals is not compromised. If required the Attending Veterinarian is available to provide one-on-one training with members of the research/surgical team. The Attending Veterinarian may choose to be present for an initial anesthetic procedure, if deemed appropriate in the pre-surgical consultation. If modifications or additions to the anesthetic protocol need to be made after an anesthetic procedure is initiated, the Attending Veterinarian determines the anesthetic and modifications to be used based on the animal's condition and consultation with the Principal Investigator.

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

Euthanasia agents and methods are determined based on recognized authoritative sources such as the American Veterinary Medical Association Panel on Euthanasia. Euthanasia is performed by trained and licensed veterinary technicians, BRSF trained staff, or by the Principal Investigator or their research personnel, who have

demonstrated via training and experience, their competence in the proper euthanasia technique. If Principal Investigators or their research personnel are performing euthanasia, it is always under the approval of the IACUC and direction of the Attending Veterinarian.

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

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

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

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

The institutional entities that are involved in the planning, oversight, and operation of the institutional Occupational Health and Safety Program (OHSP) related to animal care and use consists of, and requires coordination between the research program (as represented by the Principal Investigator (PI), the Animal Care and Use Program, as represented by the Attending Veterinarian (AV), the Institutional Official (IO), and the IACUC, the Office of Environmental Health and Safety (EH&S), the Graham Health Center, and the administration (e.g., human resources, finance, and facility maintenance personnel). These entities facilitate communication and promote ongoing evaluation of health and safety in the workplace.

The Office of Environmental Health and Safety (EH&S) is responsible for the operation of the institutional Occupational Health and Safety Program related to animal care and use. The Occupational Health and Safety Program for animal care personnel addresses the identification of risks and hazards specific to working with laboratory animals and research facilities in biomedical research settings. The program was developed based on the National Research Council guide Occupational Health and Safety in the Care and Use of Research Animals.

The Office of Environmental Health and Safety is an experienced team of trained health, safety, environmental and fire protection professionals that promote a safe, healthy and compliant environment in which to

teach, learn, work, live and visit. Their goal is to manage and interpret regulatory compliance information and provide high quality training, programming, environmental stewardship, hazard prevention, emergency preparedness and emergency response services to the campus community.
Typical areas of support and service include:

- occupational safety and health
- construction safety and health
- fire and life safety
- environmental protection
- regulatory and code compliance

They provide training and consultation in many areas of safety, health, environmental protection and compliance.

The Office of EH&S is responsible for the development, implementation and management of university policies and procedures that are designed to protect employees from occupational illness/injury. Oversight committees (safety committees) charged with identifying and addressing hazards and risks in the workplace include the Institutional Biosafety Committee (IBC), Laboratory Safety Committee (addressing fire safety, environmental safety, work related injuries, and all other safety issues not covered by a specific committee), and the Radiation Safety Committee.

Employee health services are provided through the university's on-campus Graham Health Center (GHC). For emergency medical services not provided at GHC or when GHC is closed, individuals are directed to report to Ascension Crittenton Hospital's Occupational Medicine Department located just two miles from the main campus.

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 University's Office of Environmental Health and Safety (EH&S) is responsible for the development, implementation and management of university policies and procedures that are designed to protect employees from occupational illness/injury. Oversight committees (safety committees) charged with identifying and addressing hazards

and risks in the workplace include the IACUC, the IBC, the Laboratory Safety Committee (addressing fire safety, environmental safety, work related injuries, and all other safety issues not covered by a specific committee), and the Radiation Safety Committee. All recommendations of the Radiation Safety and the IBC are closely adhered to, such as prophylactic immunizations or use of protective devices.

Any potential hazards associated with the IACUC protocol other than hazards inherent with the use of and exposure to conventional laboratory animals, such as allergies, bites, scratches, zoonoses, etc., must be identified and dealt with appropriately by the principal investigator in their protocol application form.

Engineering controls and equipment to minimize exposure to anticipated hazards are considered, along with special facilities and safety equipment needed to protect the animal care and investigative staff, other occupants of the facility, the public, animals, and the environment from exposure to hazardous biologic, chemical, and physical agents used in animal experimentation.

This approach to identify work-related hazards and the processes used to evaluate the significance of these hazards in the context of duties and tasks is common for all personnel, researchers, veterinarians, husbandry staff, students, IACUC, security personnel, etc. All employees and individuals involved in the program have key roles in helping to identify work-related risks and adherence to rules and guidelines put in place to control and/or minimize these risks. The effectiveness of the occupational health and safety program is determined by

- knowing the hazard
- avoiding and controlling exposures
- training and education
- rules and guidelines
- consistency
- recordkeeping and monitoring
- commitment and coordination

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

Ongoing identification and evaluation of hazards are reviewed during the IACUC semiannual inspections of the facilities, during routine post-approval monitoring of the various approved IACUC projects, during the Annual Review of Approved Projects, and by the follow up and review

of the history of reported occupational illness an injuries that have occurred in the workplace.

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]

Work-related accidents and injuries must be reported to a department supervisor immediately. Supervisors must complete an Occupational Accident Report within 24 hours of the reported injury and forward it to University Human Resources. Timely reporting of injuries and illness ensures that unsafe situations or conditions are addressed immediately and that employees receive the appropriate care and treatment without delay. In addition, timely reporting of injuries and illnesses ensures compliance with MIOSHA Part 11. Recording and Reporting of Occupational Injuries and Illnesses.

All occupational illnesses or injuries are documented and evaluated by the Office of EH&S and the Laboratory Safety Committee. The Office of EH&S documents, investigates, and follows up on all work related injuries, thus assessments and evaluations of the program in this respect are on-going.

The extent and level of participation of personnel is based on the hazards posed by the animals and materials used, the exposure intensity, duration, and frequency of the personnel involved, and the history of occupational illness and injury in the particular workplace.

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.

Participation in the institutional Occupational Health and Safety Program related to animal care and use is required of all animal care personnel employed by the university to work in the BRSF, and recommended for all other personnel whose activities place them at reasonable risk of injury or illness. Eligible personnel (those individuals listed as research personnel on the IACUC approved protocol) are identified by principal investigators or course directors at the time they complete their Application for the Use of Vertebrate Animals (AUVA) application form for IACUC review. Individuals may also participate in the program at their own request. This includes, but is not limited to; all BRSF staff, principal investigators, researchers and their technical staff, instructors involved with animal related work, and other personnel who may reasonably be expected to come in contact with vertebrate animals (some personnel in facilities management, campus police, or custodial services). No one is exempted from personal medical evaluation. Those not included are vendors contracted with the university to perform preventive maintenance and/or repair of specific equipment. These individuals are required to carry their own certificates of insurance as a condition of contract approval. These individuals are informed about the animal allergy risks involved upon entering the BRSF.

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.

Oakland University's **Occupational Health Program for Animal Handlers** is a medical surveillance program designed to evaluate, control, and monitor Animal Handler (employee, students, research personnel, or volunteer) exposures where laboratory animals are in use. The statement of declination must be signed by an individual that has access to laboratory animal use areas, but chooses not to participate in the university's medical surveillance program. This statement can only be signed after completion of the mandatory **Research Hazards Awareness Training** course, which includes information on potential research hazards when working with or around laboratory animals including information on allergies, their signs and symptoms, associated health risks, and benefits of enrollment in the university's **Occupational Health Program for Animal Handlers**. This declination statement is not a waiver; participation in this medical surveillance program can be re-initiated

at any time. Roughly, 50% of personnel associated with the animal care and use program have declined participation in the medical evaluation program.

c) Describe provisions for assuring confidentiality of medical information.

GHC recognizes and supports patients' rights to confidential medical care. The privacy of medical information is important and GHC is committed to protecting it. It is necessary to create a record of the care and services one receives at GHC in order to provide quality care and to comply with certain legal requirements.

If the individual is 18 years of age or older or an emancipated minor (defined under Michigan law as being married, on active duty in the armed forces or by court order), their health records will be released only with their written consent.

If the individual is 16 years of age or older, all sexually related health records are confidential. This includes sexually transmitted infections, contraception and pregnancy testing. These health records will be released only with their written consent.

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

Safety considerations for individuals with incidental exposure to animal care and use are verbally cautioned of possible exposure to animal allergens before entering the facility. Signage to this effect is posted at all entrance/exit doors to the animal use areas. All persons entering the animal use areas of the facility must wear provided shoe covers, and a disposable gown to cover their street clothes. In addition, masks, gloves, hair bonnets, and safety lenses are provided for added safety.

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.

The general features of the medical evaluation and preventive medicine program, within the context of work duties, include:

1. A medical history is taken on initial employment by the examining physician.
2. A physical examination
3. Baseline spirometry test.
4. A history of allergic reactions, with referral if deemed necessary, by the examining physician
5. A chest X-ray if deemed necessary by the examining physician
6. A tuberculin skin test
7. A blood chemistry panel
8. Immunization against tetanus and rabies. Tetanus immunization is recommended for all personnel. Rabies immunization is recommended for personnel working with random-source dogs and cats or wild animals.
9. Hepatitis B vaccine

Any potential hazards associated with the project other than hazards inherent with the use of and exposure to conventional laboratory animals, such as allergies, bites, scratches, zoonoses, etc., must be identified and dealt with appropriately by the principal investigator in their AUVA form.

The responsibility for informing employees about occupational hazards, protection against hazards, and about the relationship between good personal hygiene practices and health, rests with their supervisors. Supervisors must notify employees of any possible exposure in the workplace to hazardous biological, chemical or physical agents and monitor personnel exposure directly when informed that a potential or actual hazard exists. Supervisors must provide protective devices, such as respirators and safety eyeglasses, as required. Employing units must provide noise protection devices and protective clothing (masks, gowns, gloves, shoe covers), when required. Protective clothing is provided routinely to animal care personnel. The use of protective clothing and equipment is recommended for all personnel working with animals.

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.

In case of emergencies and after hours, when GHC is closed or is unable to provide the types of services needed, occupational health services are provided through Ascension Crittenton Hospital's Occupational Medicine. Ascension Crittenton's Occupational Medicine Department is a full-service department staffed by physicians who are board certified in occupational medicine.

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.

Federal regulations require that all personnel involved in animal care and use be adequately trained to perform their duties, and it is the responsibility of the Principal Investigator to insure that this training takes place. Oakland University's training program for personnel working with animals consists of three parts:

(1) Specific, project related training provided by the principal investigator.

(2) Completion of IACUC required Collaborative Institutional Training Initiative (CITI) Program Training courses covering species-specific courses for species used in the IACUC approved protocol, and the course titled, "Working with Animals in Biomedical Research – Basic Course", of which a Refresher Course is to be completed every 3 years thereafter.

(3) Completion of the Office of Environmental Health and Safety's (EH&S) courses:

• Research Hazards Awareness Training - This is a mandatory course for individuals working with laboratory animals or frequenting an

area where laboratory animals are used. This course provides details on Oakland University's Occupational Health Program for Animal Handlers. Trainees are provided a general overview of the potential hazards encountered when working with lab animals including animal allergies, zoonoses, personal hygiene, what to do in case of physical injuries, and other considerations regarding occupational health and safety. This course also provides a comprehensive review of Oakland University's Medical Surveillance program for animal allergy management.

- Laboratory Safety Training - This course is required for all Oakland University personnel and students that work in or around the laboratories where hazardous work may be performed, and/or where hazardous materials are handled or stored. The course details Oakland University's *Chemical Hygiene Plan* and includes instructions and training in safe standard laboratory work practices, use of personal protective equipment, health and safety information for chemical hazard classes, SDS, and toxicology overview. Training also reviews emergency preparedness and response procedures.
- If the IACUC protocol has a corresponding IBC, a Radiation Safety Committee (RSC), or an IRB application, then any required training associated with those applications needs to be completed also.

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.

Surgical masks, N95 respirators, eye protection, protective gowns, gloves, and shoe covers/rubber boots are used in dirty cage wash as needed or required. All dirty rodent and laboratory animal bedding is removed from cages using a negative airflow bioBubble® dumping station. Noise reduction headphones are available for use when running the Tunnel Washer and the Rack Washer.
Surgical masks, eye protection, gloves, and protective gowns are worn in the necropsy room at the time of necropsies.
Additional disposable gowns, caps, masks, gloves and eye protection are provided as needed. Other personal protective equipment such as N95 respirators can be provided if needed after required fit testing. Laminar flow chemical fume hoods, bio-safety cabinets, and transfer station, are used as deemed necessary by the IACUC or the pertinent university safety committee.

Principal Investigators and their research staff, ancillary staff, visitors, etc., must wear shoe covers and disposable gowns upon entering the facility. Additional PPE such as, gloves, eye protection,

face masks, must be worn when performing procedures or working with the animals. Posting of special equipment, procedures, and practices is clearly identified in all areas in which hazardous agents are used. The BRSF manager ensures that both facility staff and research personnel adhere to procedures as outlined and mandated by the IACUC and appropriate university safety committees.

b) Describe arrangements for laundering work clothing.

A dedicated washing machine and dryer are located in the Laundry Closet room 134 BRSF. BRSF staff is responsible for laundering all soiled work clothing generated by BRSF staff. Work clothing is decontaminated using fragrance and dye-free laundry detergent and ¾ cup of chlorine bleach (8.25%) and hot water with each load. No soiled work clothing is not allowed to be taken out of the facility to be laundered.

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

Sinks and soap dispensers are present in all animal housing rooms, procedural rooms and support areas, except for the four animal housing rooms (two sets of two each) that have direct access to an adjacent procedure room which contains a hand sink and soap dispenser. Hand washing is the most effective practice in reducing the potential of exposure to infectious material. Hand washing should be performed:

- at the start of the work day
- upon leaving for breaks, before meals, before and after restroom breaks
- when returning to work
- after handling of any live animal or animal tissue
- after handling any other potential source of contamination

Shower and changing facilities are provided within the BRSF and are available at all times.
Facility-provided scrubs are worn during work hours. Personnel must change back into their street clothes if they plan to leave the facility, as no work clothes may be worn outside the animal facility.
Shower and changing facilities are provided within the facility and are available at all times.

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

Smoking is prohibited in all facilities and buildings of Oakland University. The conference room and administrative offices are the only areas designated for eating and drinking within the facility.

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).

New hires must attend “Right to Know” training and then must participate in documented site-specific training provided by their supervisor. Laboratory personnel must attend “Laboratory Right to Know” training and non-lab personnel must attend “Michigan Right to Know” training. Right to Know training describes Hazard Communication requirements including the use of Safety Data Sheets (SDS) which are available in hardcopy on-site in the facility.

Below is a list of available training modules, which are assigned to personnel based on their job function. Refresher training frequency occurs based on regulatory requirements for each training module. All trainings are conducted by an instructor from EH&S except for online trainings which are noted with an asterisk (*).

a) General Lab Safety (Laboratory Right to Know)
b) Biosafety Level 1 & 2
c) Animal Biosafety Level 1 & 2
d) Bloodborne Pathogen Exposure Control*
e) Radiation Safety-Basic Nuclide*
f) Radiation Awareness Training (Includes Animal Allergy)*
g) Analytical X-Ray and Radiation Producing Machines Safety
h) Laser Safety*
i) Robotics Safety
j) Hazardous Materials and Waste Management*
k) Shipment of Biological and Hazardous Materials
l) Laboratory Lock Out/Tag Out

The BRSF manager is responsible for overseeing and ensuring adherence to general safety procedures as well as specific procedures indicated by the institution’s IBC and RSC. These committees also set their own requirements for reporting and follow-

up. Any animal housing or procedural areas requiring special precautions are clearly identified. Special precautions are posted in these areas.

Equipment is provided, and procedures are established to ensure the safety of personnel from physical hazards. Restraint and special housing devices are in place to reduce risk to the person and animal when animals must be handled.

Personnel involved in animal care or use are encouraged to wear facemasks and protective clothing when working with any animals or in animal rooms to decrease the chance of developing allergies associated with animal hair, dander, and urine. They are required to wear PPE when working with animals. Nitrile gloves are available for anyone with latex or vinyl allergies.

Disposable gowns, caps, masks, gloves, eye protection, and shoe covers are provided. BRSF staff wear facility-provided scrubs. Laundry is done in the facility, by facility staff, on a regular basis. The animal facility has been designed and constructed to minimize and confine noise. When staff work with heavy washing equipment in noisy areas noise suppression headphones and hearing protection are provided.

A chemical fume hood is located in the diagnostic lab, Room 110. There is also a portable Bio-safety Cabinet (Class II, Type A1) and portable animal transfer station available for use in the facility. The Necropsy room contains a downdraft necropsy table. The facility is also equipped with two Class II, Type B2 Biosafety Cabinets, one portable transfer station, and in Dirty Cage Processing, the soiled bedding is removed from the cages using a negative flow bedding disposal unit called a bioBubble® and bagged for disposal.

Five gallon containers of chemical disinfectants and detergents are used in the Rack and Tunnel Washers for decontamination purposes. Only the amount needed for running the equipment is kept in the facility at any one time.

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

The objective of exposure control is to prevent or minimize occupational exposure to laboratory animal allergens (LAA), thus reducing the incidence and prevalence of allergic disease while

relieving symptoms among those individuals who are sensitive. No clearly established threshold for allergen exposure supports a minimum safe exposure level; however, studies indicate that reduced exposure will reduce symptoms and decrease the incidence of laboratory animal allergy.

The principle route of exposure to animal allergens is inhalation of aeroallergens. Direct skin and eye contact can also be a common route of exposure and, occasionally, ingestion. Percutaneous exposures may result from animal bites, needle punctures contaminated with animal allergens, or allergen contamination of wounds. The most likely sources of allergens is from hair, dander, or fomites found in the air or from direct contact with the animals housed within the facility. The BRSF is a secured facility so that only individuals properly trained and approved by the IACUC to work on a protocol are allowed entrance. This training includes their having to complete the mandatory, “Research Hazards Awareness Training”, in which participants are introduced to and educated about the potential for developing LAA, and the steps they can take to reduce their exposure to LAA.

Allergen exposure stemming from occupational sources experienced by individuals who are not directly involved in the care and use of laboratory animals is also considered. Vendors, ancillary staff, and visitors are required to pre-arrange their visits to the facility. This allows for control over who is given access to the facility. All first-time entrants are instructed about the possibility of exposure to LAA, and are introduced to the personal protective equipment (PPE) that is available for them to wear to lessen their exposure to LAA.

The BRSF is designed so that the administrative offices are separate from the animal surgical areas and the animal housing rooms. The doors, linking the administrative offices to the animal surgical areas and the animal housing rooms are kept closed when not in use.

The BRSF operates on 100% fresh air, with air changes occurring within the animal housing rooms to occur at a rate of 8-37 air changes per hour (ACHP). This allows for much of the potential allergens to be removed from the air. Sufficient air volume, measured in air changes per hour, is distributed throughout the room in effective airflow patterns to mix and dilute the air to provide acceptable ventilation. This mixing of the air, termed ventilation efficiency or ventilation effectiveness, is a function of multiple factors including air volume, velocity, and temperature; ventilation

configuration and diffusion patterns; ventilation system balance; room configuration and spatial dimensions; and room heat loads.

In addition, the exhaust air from each of the animal housing rooms is filtered before being discharged into the outdoor environment. To further limit the spread of air-borne allergens, doors to the individual animal housing rooms remain closed when not in use,

PPE, such as disposable gowns, caps, masks, gloves, eye protection, and shoe covers are provided upon entry into the animal use areas to help lessen the possibility of individuals coming into direct contact with allergens.

To aid personnel in further protection from allergens, the facility is equipped with a chemical fume hood which is located in the diagnostic lab, Room 110. There is also a portable Bio-safety Cabinet (Class II, Type A1) and a portable animal transfer station available for use in the facility. The Necropsy room contains a downdraft necropsy table so that allergens are directed away from the user. The facility is also equipped with two Class II, Type B2 Biosafety Cabinets, one portable transfer station, and in Dirty Cage Processing, the soiled bedding is removed from the cages using a negative flow bedding disposal unit called a bioBubble® before it is bagged for disposal.

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

The common routes of exposure to zoonotic infectious agents are inhalation, inoculation, ingestion and contamination of skin and mucous membranes.

Inhalation hazards may arise during work practices that can generate aerosols. These include the following: centrifugation, mixing (e.g., blending, vortexing, and sonication), pouring/decanting and spilling/splashing of culture fluids. Inoculation hazards include needle sticks and lacerations from sharp objects. Ingestion hazards include the following: splashes to the mouth, placing contaminated articles/fingers in mouth, consumption of food in the laboratory, and mouth pipetting. Contamination of skin and mucous membranes can occur via splashes or contact with contaminated fomites (e.g., towels, clothes, pens, etc.).

Workers are trained to adhere to the following good practices to prevent exposure to zoonotic diseases when working with research animals:

- Avoid use of sharps whenever possible. Take extreme care when using a needle and syringe to inject research animals or when using sharps during necropsy procedures. Never remove, recap, bend, break, or clip used needles from disposable syringes. Use safety engineered needles when practical.
- Keep hands away from mouth, nose and eyes.
- Wear appropriate PPE (i.e., gloves, gowns, face protection) in all areas within the animal facility.
- Wear tear-resistant gloves to prevent exposure by animal bites. Micro-tears in the gloves may compromise the protection they offer.
- Remove gloves and wash hands after handling animals or tissues derived from them and before leaving areas where animals are kept.
- Use mechanical pipetting devices (no mouth pipetting).
- Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take or apply medicine in areas where research animals are kept.
- Perform procedures carefully to reduce the possibility of creating splashes or aerosols.
- Contain operations that generate hazardous aerosols in BSCs or other ventilated enclosures, such as animal bedding dump stations.
- Wear eye protection.
- Wear head/hair covering to protect against sprays or splashes of potentially infectious fluids.
- Keep doors closed to rooms where research animals are kept.
- Clean all spills immediately.
- Report all incidents and equipment malfunctions to the supervisor.
- Promptly decontaminate work surfaces when procedures are completed and after surfaces are soiled by spills of animal material or waste.
- Properly dispose of animal waste and bedding.
- Workers should report all work-related injuries and illnesses to their supervisor immediately.

- Following a bite by an animal or other injury in which the wound may be contaminated, first aid should be initiated at the work site.

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

All equipment is operated, cleaned, and disinfected according to manufacturer recommendations.
The three biosafety cabinets, the portable transfer station, the chemical fume hood, and the bioBubble® are annually certified to manufacturers' specifications by a commercial quality testing service.

e) Respiratory Protection

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

Soiled bedding is removed from the cages using a negative flow bedding disposal unit called a bioBubble® and bagged for disposal. In addition to safety goggles, noise suppression headphones, gloves, scrubs, and face masks are part of the required PPE. If N95 respirators are needed for this or other research protocols that would require the wearing of a respirator then Oakland University's Office of Environmental Health and Safety personnel would work with the employee or research staff personnel to identify the correct mask and type to use. Graham Health Center personnel then works with the individual in training them in the proper use and maintenance of the respirator.

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

In conjunction with the mandatory annual health physical, BRSF staff attend mandatory annual respirator fit-testing through the Office of Environmental Health and Safety and the Graham Health Center. All staff are trained in accordance with requirements of MIOSHA Part 451-Respiratory Protection.

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

Respiratory protective equipment is selected on an individual basis according to design, fit, and ease of use, with the maximum protection available. Respiratory protective equipment function is assessed by the wearer prior to each use and annually during the mandatory fit-testing.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

In efforts to ensure personnel safety, all staff receives one-on-one training on how to operate the Rack and Cage Washer, the Tunnel Washer, and the two autoclaves. Safety signage and SOPs are posted on or next to the machines. On occasion equipment manufacturer representatives are invited to give equipment operation demonstrations and training as needed. In addition, the vendor contracted to provide preventive maintenance on the equipment hosts training sessions upon request. All personnel are required to wear appropriate personal protective equipment when operating the machinery. Noise suppression headphones are required when operating the Tunnel Washer.

Specific attention to built-in safety features, such as emergency stops and pull cables for shutting off the water and de-energizing the machines, are discussed and demonstrated. It is mandatory that all BRSF staff attend training specific to running and operating the walk-through Rack and Cage Washer. Staff have to demonstrate their ability to get out of the machine in an emergency situation, and show that they understand how to use the safety cables. Only BRSF staff is allowed to operate the autoclaves and decontamination equipment. The Autoclaves and Rack/Cage Washer are turned off at the end of each day before staff leave the facility.

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.

There are none.

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.

There are no motorized vehicles used for animal transport.

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

Personnel filling anesthetic vaporizers must do so in a well-ventilated area, wear nitrile exam gloves, and perform this procedure at the end of the day if at all possible. Wall chains or other restraint devices secure all compressed gas cylinders. All areas within the animal facility where gas anesthetics may be used have been constructed for external active exhaust scavenging. Waste anesthetic gases are removed by an active scavenging system. The flow to the exhaust/scavenge, on each of the anesthetic machines, can be set at minimum or maximum flow. Connections to scavenge waste gases hang down from the ceilings in the OR's at each of the gas supply line stations in the form of metal piping of medium bore. The anesthetic machine is checked for leaks prior to each use. The waste anesthetic gas hose from the anesthetic machine is connected to an exhaust ceiling drop. The updraft of the exhaust flow actively removes the waste gases from the anesthetic system.

A policy and written standard operating procedure (SOP) addresses the use of Delivery of Inhalant Anesthetics Using a Bell Jar which provides guidance for principal investigators and their staff when delivering inhalant anesthetics while performing genotyping procedures on rodents. In these instances the procedures need to be performed utilizing a chemical fume hood or a biosafety cabinet exhausted through a canopy connection to protect the safety of personnel and to ensure that any waste gases are correctly exhausted via the equipment being used. To insure the safety of all staff EH&S has also implemented an SOP and program for

monitoring personnel and the work area while using inhalant anesthetics.

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.

Human cell lines – BSL2
Plasmids – BSL1
Batrachochytrium dendrobatidis (Amphibian Chytrid fungus) – BSL2

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

Streptozotocin (STZ)
Sodium Selenite – irritant, mutagen
Zinc Chloride – irritant, mutagen
N-ethyl N-methyl nitrosourea (ENU) – Mutagen
Lipopolysaccharide (LPS) – Endotoxin-Toxic
Gonadotropin-Human Reproductive Toxin.
Dimethyl Sulfoxide (DMSO) – Irritant, Mutagen
Isoflurane – Anesthetic Agent, sever respiratory depressant
Dextran sodium sulfate – Irritant
Thioglycolate – Irritant
Fluorescein isothiocyanate–dextran – Irritant
Yohimbine hydrochloride – Oral Acute Toxin

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

O_2 Compressed Gas – Hyberbaric and O_2 Chamber
UV light - UVB

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.

All animal protocols involving the use of potential experimental hazards are assessed by the IACUC and submitted to the appropriate safety committee for review and approval prior to receiving full IACUC approval. The safety/oversight committees charged with identifying and addressing hazards and risks in the workplace include the IRB (Institutional Review Board Committee), Institutional Biosafety Committee (IBC), Laboratory Safety Committee (addressing fire safety, environmental safety, work related injuries, and all other safety issues not covered by a specific committee), and the Radiation Safety Committee.

Representatives from the safety committees are available to the IACUC and BRSF staff for questions or consultation as potential problems are identified. The Laboratory Compliance Manager with the Office of Environmental Health and Safety attends all IACUC meetings. In addition, EH&S maintains an office at the Biomedical Research Support Facility. BRSF staff has ready access to all institutional policies, including those related to health and safety.

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.

Risks of hazards are assessed by the IACUC, in conjunction with the following oversight/safety committees: the IRB (Institutional Review Board Committee), Institutional Biosafety Committee (IBC), Laboratory Safety Committee (addressing fire safety, environmental safety, work related injuries, and all other safety issues not covered by a specific committee), and the Radiation Safety Committee.

Procedures are developed and risks are managed by the Principal Investigators working with these committees to formulate standard operating procedures that identify and address any potential safety

risks. Risks associated with the experimental use of animals are identified and reduced to minimal and acceptable levels. Hazard identification and risk assessment are ongoing processes that involve individuals qualified to assess dangers associated with the Program to implement commensurate safequards. Ongoing identification and evaluation of hazards is accomplished through periodic inspections such as the Semiannual Program Review and Facility Inspections, and informal post approval monitoring inspections, and by requiring the reporting of potential hazardous conditions or “near miss” incidents, accidents, and spills.

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

All hazardous waste is managed according to the Oakland University Hazardous Waste Management Guidance Manual. Specifically all waste is properly identified with proper chemical name and/or EPA waste code. EH&S is responsible for the handling, storage, method and frequency of disposal and final disposal location for all hazardous wastes on campus. EH&S is responsible for the storing of radioactive animal wastes which contain short half-life radionuclides in freezers and holding them till they are no longer regulated as Radioactive Wastes. This includes infected or toxic, bedding, cages, medical sharps and glass. The university contracts with a commercial licensed medical waste hauler to dispose of hazardous waste on a monthly basis.

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

Personnel potentially exposed to hazardous agents are managed depending on the agent in use. Anyone working with high risk biological agents or OSHA Subpart Z hazardous agents will be enrolled in a medical surveillance program and provided a medical evaluation specific to the hazardous agent in use. Researchers exposed to hazardous agents are either evaluated by the Oakland University Graham Health Center and/or Ascension Crittenton’s Occupational Medicine Department, a full-service department staffed by physicians who are board certified in occupational medicine.

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.

Those who purchase and work with hazardous materials are trained in the importance of hazardous waste minimization strategies and the methods utilized in their areas through EH&S.

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.

Rooms and facilities used to house animals exposed to hazardous agents are assigned accordingly under the direction of the IACUC and any corresponding safety committee recommendations. Specific recommendations from safety oversight committees are adhered to for all projects involving potentially hazardous agents.

The animals that are to be infected ENU, LPS, and Scarb I Adenovirus are housed in the Biocontainment Suite in micro-isolator caging, with all inoculations, procedures, manipulations, and cage changes being conducted within biosafety cabinets. The Biocontainment Suite is exclusively used for BSL1 and BSL2 containment procedures. The exterior of the cages are disinfected with a clidox solution before being removed from the biosafety cabinet. Caging and bedding from animals infected with human stem cells are autoclaved before being removed from the Biocontainment Suite or the animal housing room for normal dirty cage processing. All chemical agents are prepared and handled in a chemical fume hood or biosafety cabinet. All personnel are required to wear protective goggles, lab coat, face mask, and gloves when handling these substances.

Animals injected with human stem cells, sodium selenite, zinc chloride, and STZ are housed in micro-isolator caging in their prospective animal housing rooms. All injections, inoculations, procedures, manipulations, and cage changes are conducted within biosafety cabinets or the animal transfer station. The contaminated bedding is removed from these cages using a negative airflow bioBubble® dumping station, and collected in waste bags for disposal through the university's licensed medical waste hauler.

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.

Circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities, such as the Biocontainment Suite, come under the guidance and recommendation of the IACUC and corresponding safety committees. This is due, much in part to the increased use of hazardous materials in the research protocols and the lack of dedicated containment space within the facility. When BSL1 and BSL2 work is IACUC approved to be performed outside of the Biocontainment Suite, all practices and procedures, specific to the protocol, follow written standard operating procedures that are posted within each room. In addition, these animal housing rooms are put into lock down where only those individuals with the proper training and IACUC approval are able to access the rooms using a Personal Identification Number (PIN) assigned to them by the BRSF Manager .

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

A chemical fume hood is located in the diagnostic lab, Room 110. A portable Bio-safety Cabinet (Class II, Type A1) is available for use in the facility. The Necropsy room contains a downdraft necropsy table. The facility is also equipped with two Class II, Type B2 Biosafety Cabinets, one portable transfer station, and in Dirty Cage Processing, the soiled bedding is removed from the cages using a negative flow bedding disposal unit called a bioBubble® and bagged for disposal.

All equipment is operated, cleaned, and disinfected according to manufacturer recommendations.
The three biosafety cabinets, the portable transfer station, the chemical fume hood, and the bioBubble® are annually certified to manufacturers' specifications by a commercial quality testing service

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

Equipment is provided, and husbandry practices and procedures are established and written to ensure the safety of personnel from physical hazards. Restraint and special housing devices are in place to reduce risk to personnel when animals must be handled.

Personnel involved in animal care or use are encouraged to wear facemasks and protective clothing when working with any animals or in animal rooms to decrease the chance of developing allergies associated with animal hair, dander, and urine.

Disposable gowns, caps, masks, gloves, eye protection, and shoe covers are provided. BRSF staff wear facility-provided scrubs.

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.

Presently there are no animal-and human-based research protocols.

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.

When IACUC approved transportation of animals from the BRSF to investigators' laboratories in Dodge Hall for the purpose of imaging, or euthanasia when immediate tissue removal is required, the animals are transported in ventilated containers directly to the researcher's lab with minimum exposure to common hallways. All cages are covered with drapes and only the service elevator is used between floors to minimize and potential contact with individuals not associated with the animal care and use program.

B. Program Oversight

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

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]
Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

i. Describe Committee membership appointment procedures.

IACUC members are appointed by the university president, on the recommendation from the Associate Vice President for Research and Institutional Official to the Public Health Service, NIH, the United States Department of Agriculture, and the IACUC. Committee appointments are for a term of one to three years, and are renewable.
Two member positions are determined by positions held with the university. These are the positions of Attending Veterinarian and the University Surveillance Officer (the Animal Research Facility Manager is also the University Surveillance Officer). Both of these position terms are position permanent – as long as positions as Attending Veterinarian or University Surveillance Officer are held.

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

The IACUC meets monthly for full committee meetings and conducts special meetings as determined necessary by the IACUC chair. Additionally, a sub-committees of the IACUC meets every six months to conduct semi-annual Program Reviews and Facility Inspections.

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

Training of IACUC members is ongoing. All members are provided copies of the:

- PHS Policy
- Guide for the Care and Use of Laboratory Animals
- USDA Animal Care BlueBook – Animal Welfare Act and Regulations
- Arena/OLAW IACUC Guidebook and a copy of the most recently approved Animal Welfare Assurance Statement
- AVMA Guidelines on Euthanasia 2013
- ACLAM Guidelines for Pain Management for Rodents
- Guidelines For Use of Fish in Field Research
- Guidelines for Use of Live Amphibians and Reptiles
- Access to Oakland University's Training and Information Manual for Animal Care and Use

IACUC members are required to complete the CITI Program course entitled, Essentials for IACUC members. New members are required to attend an orientation/tour of the Biomedical Research Support Facility. Reprints of pertinent IACUC related articles pertaining to animal research are often discussed and distributed to all members at committee meetings. Copies of past documents relating to the animal care and use program such as meeting minutes, semiannual inspection reports, USDA inspection reports, etc., are available upon request. The IACUC Administrator also

keeps the IACUC apprised of any notices from OLAW relevant to OU's program. (https://grants.nih.gov/grants/olaw/references/notices.htm) Committee members are encouraged and given the opportunity to attend local conferences relating to animal research issues, such as those which are routinely offered by the Michigan Society for Medical Research (MISMR).

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

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

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

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

The responsibility of scientific merit review normally lies outside the IACUC. For proposed protocols in which the funding/review process is internal to Oakland University, the department chairperson – who signs off on all submissions – serves as the individual accountable for scientific merit review. The committee members do evaluate scientific elements of the protocol as they relate to the welfare and use of the animals. Some of these elements are hypothesis testing, sample size, group numbers, and adequacy of controls as these may directly relate to the prevention of unnecessary animal use or duplication of experiments. If needed outside experts may be invited for advice and opinions. IACUC members named in protocols or who have other conflicts of interest must recuse themselves from decisions concerning these protocols.

The IACUC established a pre-review process of IACUC applications as a support mechanism for PIs. The purpose of the process is meant to be a consultation-type educational service to PIs, as well as to streamline the time spent by the committee in reviewing applications. The IACUC highly encourages first-time applicants and applicants proposing to use a different species in their current projects to use this resource.

As part of the IACUC protocol review process the committee evaluates whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcomes of the project by taking into account ethical considerations, and benefits to human beings, animals, or the environment. **This harm-benefit analysis weighs the potential adverse effects or harm to the animals against the benefits the will likely result from the proposed project**. This analysis is an integral component of the review process. To help the IACUC in this process, the Principal investigator is required to list in the IACUC application, the benefits to be gained from the study and to explain how the information gained will benefit human or animal health, the advancement of knowledge, and/or serve the good of society. This ethical justification depends on the balance between the benefits (primarily to humans) and the costs to experimental animals in the form of pain, distress, and euthanasia. These ethical expectations are embodied in the principles of the *Three Rs*: replacement, refinement, and reduction. To this end the PI is also required in the IACUC application, to explain why they cannot replace, refine, or reduce their animal use numbers.

In reviewing protocols that include procedures that have not been previously encountered or that have the **potential to cause pain or distress** that cannot be reliably predicted or controlled the IACUC seeks relevant objective information about the procedures and the purpose of the study. Sources for this information may come from literature, veterinarians, investigators, and others knowledgeable about the effects on animals. If little is known about a specific procedure the IACUC may request pilot studies be performed and conducted under the oversight of the IACUC. These studies would be designed to assess both the procedures' effects on the animals and the skills of the research team. If the IACUC requests a pilot study be conducted, the PI is required to report the pilot study results back to the IACUC for review prior to approval for an initiation of the continuation of the study. If the protocol involves the potential for animals to experience levels of pain, discomfort, or distress that cannot be classified as those for which pain-relieving drugs would not be customarily given in human medicine or standard veterinary medicine (USDA Pain Category C), the applicant is **required to consult the Attending Veterinarian for input and consultation** prior to submitting their application. During this consultation, the Attending Veterinarian may make recommendations to alleviate associated pain or potential distress and advises the PI on the appropriate analgesic and anesthetic agents to be used that are specific to species and procedures proposed.

For protocols with the potential for unrelieved pain or distress the IACUC weighs the objectives of the study against potential animal welfare concerns. Consideration of refinement, use of appropriate non-animal

alternatives to replace the use of animals, and the reduction in the number of animal used are considered and addressed by the IACUC to ensure humane animal care and use.

The IACUC requires that all animal numbers and **experimental group sizes are justified**. In the IACUC application the Principal Investigators (PI) are asked to: Describe the alternatives to the use of live animals that have been considered and why they cannot be used to obtain the desired data. The PI is required to explain why group variances, if unknown, would require a pilot study or preliminary project, to indicate how much tissue is needed and how much tissue would be expected to be obtained from each animal if the group size is based on the quantity of harvested cells or amount of tissue required, and to provide any statistical analysis used in determining group sizes. If other means are used to determining group sizes, the criteria used needs to be indicated. Specific calculations, flow charts, algorithms, etc., may be required by the IACUC for more complex study designs.

An investigator must submit, the IACUC's Application for Use of Vertebrate Animals in Research, Teaching or Testing (AUVA form; enclosed in appendix section III.-5), electronically through the university's Research Application Manager (RAM) system. Once entered into the system IACUC members receive an email informing them that an IACUC application has been added to their work list and requests the member to log into the system to review the application.

New applications or submissions requesting significant changes of a currently approved application are requested to be submitted a minimum of ten days prior to the next scheduled IACUC meeting. Although all IACUC members have access to the RAM system, hardcopies of all meeting materials are also mailed to the committee's non-affiliated/community representative and Attending Veterinarian to assist them with their review. Applicants are informed of their proposal being placed on the meeting agenda and invited to be available for attendance during the meeting if requested by the committee. Applications are reviewed and discussed by the members in attendance. If a member cannot attend a scheduled meeting, they are requested to notify the Chairperson prior to the meeting and inform them of the status of their review of pending proposals so that this information can be relayed to members in attendance. After committee discussions and deliberations, if there is any further input required from the applicant, they are invited into the meeting to respond to any remaining comments or questions that the committee may have. The applicant is then excused from the meeting and final committee discussions take place cumulating with a vote for full approval, modifications required to secure approval, or withhold approval of the proposal.

If the IACUC tables protocol review/approval, the reasons for the IACUC's decision are communicated to the PI, and the committee appoints a member to work directly with the PI (if needed) to help the PI in addressing the committee's concerns and comments. The PI is then invited to resubmit the protocol once the IACUC's concerns and comments have been addressed.

Principal Investigators are required to submit one original application that is signed by the PI and Department Chairperson, as well as other related documents (if applicable). At the time of signature, each individual discloses if he/she or immediate family members have a conflict of interest (COI) with the sponsor of the project. The IACUC considers these disclosures and their management, if applicable, during review of the proposed project. Per Oakland University's Conflict of Interest Policy, principal investigators and other persons involved in the design, conduct, or reporting of funded research are required to disclose to the university any significant financial interest (including those of spouses and dependent children). A conflict will be deemed to exist when it is reasonably determined that a significant financial interest may directly and significantly affect the design, conduct, or reporting of research. The university is then required to manage, reduce, or eliminate the conflict via the determination of a COI committee. Any management plan that results from this process is provided to the IACUC.

Principal Investigators, who have current IACUC Project Approval Periods greater than one year, but less than three years, are required to submit a properly completed, "Annual Review of Approved Projects" form to the IACUC within 30 days of the yearly anniversary date(s) of their original IACUC approval. IACUC members are notified of annual review forms submitted and are given access to the forms 7 days prior to a scheduled meeting. The annual reviews forms are then reviewed by full committee review (FCR). All ongoing projects receive a complete and new review by the IACUC every three years.

At the completion of the project the Principal Investigator is required to submit the IACUC's Project Completion Summary Form. If a proposal application requires more than three years to complete, a new AUVA form is required to be submitted and approved by the IACUC two months prior to the end of the initial three year approval period.

No projects involving the use of vertebrate animals may commence without written IACUC approval.

The Oakland University IACUC allows only two valid methods of IACUC review:

1) full-committee review by a convened quorum of the members of the IACUC
2) designated member review by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review

Convened Meeting:

- IACUC meetings are scheduled on a monthly basis but may be cancelled if there is no business on the agenda or ad hoc meetings may be scheduled as necessary.
- A quorum (greater than 50% of the voting membership) must be present for all committee votes.
- IACUC members having a Conflict of Interest, as defined by the OU Conflict of Interest policy, must recuse themselves during deliberation and voting except to provide specific information requested by the IACUC. Members may never vote on a protocol for which they are principal investigator or responsible faculty member.
- Recused member(s) must not be counted as part of the quorum for voting purposes.
- Members have access to protocols electronically at least seven days before the meeting.
- All members are expected to attend and participate in the full committee reviews at the convened IACUC meeting.
- The IACUC Chair may invite consultants to assist in the review of complex protocols, but consultants cannot vote unless they are officially appointed voting members on the committee.

Designated Member Review:
When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR), or returned for FCR at a convened meeting. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:

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 required modifications are needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

In order to conduct reviews by DMR subsequent to FCR, this IACUC has specified its intention to conduct reviews in this manner in its Assurance with OLAW.

To conduct DMR, the following conditions must be met: all members of the IACUC must be given an opportunity to call for FCR, either for each individual protocol or by previously established written standard procedure, as described above. If, and only if, no member requests FCR, the protocol may be reviewed by one or more qualified members appointed by the Chair.

DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. DMR may not result in withholding of approval.

If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if additional required modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the additional required modifications.

The specific method of review for each protocol is documented, along with the outcome of the review in the IACUC meeting minutes

Designated review may be used in the following situations:

1. Revisions made to a previously approved study
2. Review of required modifications requested by the convened full committee.

Designated member review (DMR) may not be used in the following situations

1. New Protocols
2. An IACUC member requests a full committee review (FCR) within the allotted seven- day period.
3. Studies which are determined to be Pain Category E

Administrative/Non-significant Revisions/Changes

Request for administrative or non-significant revisions/changes to previously approved protocols may be approved administratively by the IACUC Chair in consultation with the IACUC Administrator and Animal Research Facility Manager. These administrative changes are reported to the full committee at the next meeting and are noted in the minutes. Examples of non-significant changes include, but are not limited to:

- Addition or removal of project personnel other than the Principal Investigator and/or the Responsible Faculty Member
- Change in the vendor source when the source remains an approved commercial vendor
- Changes in project dates as long as the total project approval period does not exceed three years. Changes in project dates (generally delayed start dates) may be requested due to funding delays, unavailability of proposed personnel, etc.

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.

Request for Revision – Requests for revisions to previously approved projects are handled in one of three ways.

If the request is for minor administrative/non-significant revision for the addition or removal of project personnel (except for the PI or Responsible Faculty Member), to add or change the source of animals, or to add or change the funding source, the IACUC has initiated the use three IACUC amendment forms to expedite the process of administrative approval. The IACUC Chair may approve of the request on the committee's behalf after consultation with the IACUC Administrator. These forms are available on the Institution's research website. All approved IACUC amendment forms are kept on file with the IACUC protocol.

All administrative approvals are listed in the IACUC agendas and meeting minutes in order to keep the committee informed of these changes.

Requests for Major Significant changes must be submitted to the full committee for review. Major Significant changes include but are not limited to:

- Changes to study objectives
- Procedures performed on live animals
- Changes in the number of animals used in the study
- Increase in the pain category
- Changes in the strain or species of animal
- Changes in the PI or Responsible Faculty Member

The review mechanism for these changes follows the scheme outlined above.

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.

Humane endpoints are considered by the IACUC in the protocol review for all experiments involving animals, especially those that involve the potential for pain and distress. The Principal Investigator in writing the protocol, is required to list specific endpoints to be used and how these endpoints will be determined prior to IACUC approval. If the protocol involves the potential for animals to experience levels of pain, discomfort, or distress that cannot be classified as those for which pain-relieving drugs would not be customarily given in human medicine or standard veterinary medicine (USDA Pain Category C), the applicant is required to consult the Attending Veterinarian prior to submitting their application. During this consultation, the Attending Veterinarian makes recommendations to alleviate associated pain or potential distress and advises the PI on the appropriate analgesic and anesthetic agents to be used that are specific to species and procedures proposed. The IACUC requires the PI to define the specific criteria to be used to assess the welfare and status of each individual animal in the study. Examples of these criteria may include: posture, ambulation, food and water consumption, body weight, etc. If the PI proposes to alter standard criteria for these parameters, the IACUC requires the PI to provide specific justification for any alternative endpoints, and how these alternative endpoints will be monitored. In this situation, the BRSF veterinary technician staff have full knowledge of animal protocols and monitor the animals and procedures closely, and make reports to the Attending Veterinarian and the IACUC.

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

The IACUC requires the PI to produce relevant objective information about the procedures and the purpose of the study. At times, protocols include procedures that have not been previously encountered or that have the potential to cause pain or distress that cannot be reliably predicted or controlled. The PI is required to provide a written narrative description of methods and resources used to determine that an alternative was not available. In addition to alternative considerations,

the PI is required to consult with the Attending Veterinarian regarding painful procedures. The IACUC may address concerns of the Attending Veterinarian by requiring a pilot study be performed to determine the technical feasibility of a larger study, to assess the skills of the research team, and help to make initial assessments of the effect of the procedures on the animals. Pilot studies warrant heightened awareness of animal care and welfare. Therefore, the IACUC requires the research and animal-care staff be aware of potential concerns or complications that may arise during the pilot study. For studies in which humane alternative endpoints are not available, research and animal-care staff perform both general and study-specific observations of the research animals at appropriate time points. The IACUC approves the assessment criteria and the required responses are clearly defined in written standard operating procedures, and the use of study-specific animal assessment records, such as weight charts, clinical body condition score sheets, etc. are employed. These records come back to the IACUC as part of the annual review to help them determine if the study should proceed.
The IACUC also requires the PI to consider the availability and appropriateness of less invasive procedures or require refinements to methodology that improve animal wellbeing. If refinements occur or if new procedures become available then these are identified and implemented with the intention to reduce harm to the animal while meeting scientific objectives.

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

All personnel working with the animals are responsible for monitoring animals for potential pain and distress, but in these instances the IACUC requires the Principal Investigator to identify the individual responsible for monitoring of the animals condition in the protocol. This individual is responsible for all written records associated with the monitoring of these animals. All individuals working with the animals must complete the required CITI Program Training Course that is species–specific to the animals used in the protocol. Study-specific training is provided by the PI. In addition, the Attending Veterinarian and BRSF staff also monitor the animals for pain and distress. Communication is two way – BRSF/AV can communicate to project personnel when animals are in distress and modifications to the study design or husbandry are necessary.

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.

The Attending Veterinarian and IACUC members may visit the facility or individual labs where animals are used, at any time, including during animal manipulations and procedures. The veterinary technicians have full knowledge of animal protocols and monitor the animals and procedures closely. Deviations in approved protocol procedures and reports of ongoing activities, especially those that relate to unexpected outcomes of the experimental procedures, are provided to the Attending Veterinarian by the BRSF manager as they occur. Additionally, the BRSF manager attends IACUC meetings and reports are given as to ongoing activities to all IACUC members. The IACUC has initiated the use of a new standard operating procedure (SOP) entitled, "Guidance on Prompt Reporting of Unanticipated Problems and Unexpected Deaths of Research Animals". Adverse events are identified as instances of unfavorable or unanticipated (not in the approved protocol) signs, or outcomes which can include suboptimal well-being (i.e. poor welfare), animal death, disease, distress, or trauma that was not the anticipated result of approved protocol or standard operating procedure activity. Included in the SOP is a reporting form the PI is to use to report any unanticipated problems directly to the Attending Veterinarian. Finally, reviews of ongoing activities are also conducted through the Annual Review process and the Semiannual Program Reviews and Facility Inspections.

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."

Oakland University's current IACUC protocol application addresses measures for prolonged animal restraint via identification in the body of the IACUC application and completion of a designated appendix for this specific issue. The IACUC defines "prolonged" as, conscious physical restraint greater than thirty (30) minutes in length.
During the IACUC protocol review, concerns about restraints used in the protocol are addressed, including information about acclimation or scientific justification for withholding it. Protocols that involve the use of any restraint devices must include a description of the restraint device, the purpose and scientific justification of the restraint, the duration that the restraint will be used, the period and method of acclimation of the restraint, and the expected discomfort to the animal.

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

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

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

There currently are no IACUC approved protocols that require animals to be restrained using mechanical devices for a prolonged period of time, nor have there been within the last 3 years.

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.

Multiple major survival surgeries are permitted when essential components of a single research protocol in which other methods will not achieve the research goals. They must be scientifically justified by the principal investigator in the protocol and approved by the IACUC. Multiple major survival surgical procedures may be justified if they are related components of a research project, if they conserve scarce animal resources, or if they are needed for clinical reasons. Cost savings is not an adequate reason for performing multiple survival surgeries. Justification must include an explanation of the need to have an animal undergo multiple major survival surgeries, a description of the procedure(s), the total number of surgeries an animal will undergo, the frequency of the procedure, the period of time between procedures, and the methods used to minimize pain and distress. It is recommended that the principal investigator provide references when possible. If the surgeries are clinically necessary for the health of the animal, then this determination must be made in consultation with the Attending Veterinarian.

The number of survival surgeries must be limited to the minimum number to achieve the research objectives and must be determined with

due consideration to minimizing pain and distress on any one animal. Some procedures categorized as minor may induce substantial postoperative discomfort and should similarly be described and scientifically justified in the protocol if performed multiple times on one animal.

If multiple major survival surgical procedures are approved by the IACUC, particular attention must be provided by the research staff to animal health and well-being through frequent and continuing evaluations, and the IACUC must evaluate outcomes of multiple surgical procedures.

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.

There currently are no IACUC approved protocols involving multiple survival surgery (major or minor) on a single animal.

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.

This information is provided in a chart in Appendix Number 18.

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

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

The use of non-pharmaceutical-grade chemicals or substances must be strongly justified in the animal use protocol. For all species, permission must be obtained from the IACUC to administer any non-pharmaceutical chemical compounds. Justification for the use of non-pharmaceutical agents may include availability of suitable pharmaceutical grade drugs or scientific necessity. Cost in itself in not typically considered an adequate reason to employ non-pharmaceutical chemical compounds. Any non-pharmaceutical chemical agents administered in survival and non-survival studies, and animal experimentation must meet quality control and assurance standards which must be addressed in the IACUC protocol application in the form of a written standard operating procedure (SOP). Factors included in the SOP are:

- Appropriate drug reconstitution, preparation and/or compounding
- Drug purity, sterility, pH, osmolality, concentration, et cetera
- Drug safety, efficacy, and shelf-life
- Training, experience, and performance of personnel involved
- Responsibility for monitoring preparation and use
- Site and route of administration
- Side effects and adverse reactions
- Storage and pharmacokinetics

*Not all factors may be applicable.
*If the "shelf life" is not obtainable, it is recommended that the drug solution be re-prepared each day it is used.
Non-pharmaceutical-grade chemicals or substances can be used only if a veterinary or human pharmaceutical-grade product is unavailable or when the use of such substances is necessary to meet the scientific goals of the project. When approving such substances for use in a protocol the IACUC gives careful consideration to the grade, purity, sterility, PH pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmocokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use.

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.

Special considerations used by the IACUC when reviewing field investigations of animals are to: Require the principal investigator to obtain any international, federal, state, and/or local permits, necessary so that

proper evaluation of the scientific merit of the proposed study and its potential impact on the populations or species to be studied can be determined. Requires review of occupational health and safety issues, including zoonoses, by the institutions health and safety office to ensure the IACUC that the field study does not compromise the health and safety of either animals or persons in the field. Requires that the principal investigator conducting the field research to be knowledgeable about relevant zoonotic diseases, associated safety issues, and any laws or regulations that apply. Exceptions to this must be clearly defined for evaluation by the IACUC. The Attending Veterinarian is available for consult if needed for sedation, anesthesia, surgery, recovery, transportation, euthanasia, etc.
When species are removed from the wild, the principal investigator must include in his protocol, plans for either the return of the animals to their habitat, or their final disposition as is appropriate.

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

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

Principal Investigators are strongly discouraged from advocating animal reuse as a reduction strategy. Live animals that have already undergone experimental procedures are not reused.

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.

Live animals that have already undergone experimental procedures are not reused.

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.

Live animals that have already undergone experimental procedures are not reused. Animals can be adopted by research personnel under special circumstances.

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).

No projects involving the use of vertebrate animals can commence without written IACUC approval,

Principal Investigators, who have current IACUC Project Approval Periods greater than one year, but less than three years, are required to submit a properly completed, "Annual Review of Approved Projects" form to the IACUC within 30 days of the yearly anniversary date(s) of their original IACUC approval. IACUC members are notified of annual review forms submitted and are given access to the forms 7 days prior to a scheduled meeting. The annual reviews forms are then reviewed by full committee review (FCR). All ongoing projects receive a complete and new review by the IACUC every three years.

The AV and BRSF staff are consistently involved in post-approval monitoring and report events to the IACUC at regular meetings or at special meetings if required.

At the completion of the project the Principal Investigator is required to submit the IACUC's Project Completion Summary Form. If a proposal application requires more than three years to complete, a new AUVA form is required to be submitted and approved by the IACUC two months prior to the end of the initial three year approval period.

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

A subcommittee of the IACUC reviews the animal care and use program and inspects facilities semiannually using the Guide for the Care and Use of Laboratory Animals (Guide), the USDA Animal Welfare Act-title 9, chapter 1 subchapter A, the IACUC's Checklist for Review of Program and Facilities Inspection (OLAW's sample), and the previous IACUC semiannual report as resources for their evaluations. A subcommittee of the IACUC consisting minimally of at least two voting members is required for these reviews. All members have the opportunity and are encouraged to participate.

The subcommittee report is compiled into a final report that is reviewed by the full Committee. Once approved by the committee, the final report is signed by a majority of the committee members, and submitted to the Institutional Official.

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**.

A subcommittee of the IACUC reviews the animal care and use program and inspects facilities semiannually using the Guide for the Care and Use of Laboratory Animals (Guide), the USDA Animal Welfare Act-title 9, chapter 1 subchapter A, the IACUC's Checklist for Review of Program and Facilities (OLAW's sample), and the previous IACUC semiannual report as resources for their evaluations. A subcommittee of the IACUC consisting minimally of at least two voting members is required for these reviews. All members have the opportunity and are encouraged to participate. PIs and lab personnel for areas outside the BRSF are notified of the date and time of the inspection so that access to and inspection of the areas are available. The subcommittee report is compiled into a final report that is reviewed by the full Committee. Once approved by the committee, the final report is signed by a majority of the committee members, and submitted to the Institutional Official.

Animal use areas include the BRSF and areas located outside of the centrally managed area (BRSF) in which animals are housed for more than 24 hours, and/or areas where any form of surgical manipulations (minor, major, survival, non-survival) are performed. These include animal study areas where USDA covered species or animals owned by Oakland University are housed in facilities that Oakland University owns and operates.

Other monitoring procedures include unannounced site visits by: the State of Michigan Department of Agriculture and the Michigan Department of Public Health. These entities, like the USDA, are authorized to conduct unannounced site visits at any time. The Attending Veterinarian, as well as all other IACUC members may visit the facility or individual labs where animals are used, at any time, including during animal manipulations and procedures. The veterinary technicians have full knowledge of animal protocols and monitor the animals and procedures that are ongoing on a day-to-day basis. Deviations in approved protocol procedures are reported to the BRSF Manager who reports this information to the Chair of the IACUC and the Attending Veterinarian for appropriate action.

To date, there are no protocols using contract facilities, or use of contractor-provided personnel.

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.

There have been no deficiencies noted during external regulatory inspections within the past three years.

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

The veterinary technicians and BRSF staff have full knowledge of animal protocols and monitor the animals and procedures that are ongoing on a day-to-day basis. Deviations in approved protocol procedures are reported to the BRSF Manager who reports this information to the Chair of the IACUC and the Attending Veterinarian for appropriate action.

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

The IACUC reviews and discusses any expressed concerns involving the care and use of animals. Procedures for reporting deficiencies in animal care and use are covered in our training manual. A copy of the Report of Deficiencies form is also available in the manual. The Report of Deficiencies form is posted, along with multiple copies for users, on the bulletin board located in the Biomedical Research Support Facility (BRSF), the core animal care and use facility. The form can also be found in the Animal Care and Use Manual and on the IACUC webpage. The individual reporting the occurrence is directed to contact the Attending Veterinarian or Animal Research Facility (ARF) Manager. BRSF staff are instructed in the procedure for receiving reports also. In addition, the report may be sent directly to the Institutional Official through the Research Office. The form that is provided to report a deficiency clearly states that anyone reporting violations of the Animal Welfare Act shall not be discriminated against or be subject to any reprisal for making a report. Reports of concerns, concerning the care and use of animals, will be reviewed by committee members at the next convened IACUC meeting, or at a specially convened IACUC meeting if deemed appropriate by the IACUC chair or Attending Veterinarian. Recommendations about these concerns are sent to the appropriate individuals and copies get forwarded to the Institutional Official. Individuals reporting animal welfare concerns are given the option to remain anonymous.

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.

Disasters affecting animal facilities may be of three general types: natural events (related to weather or geology), technical emergencies (such as mechanical failures or chemical spills), and civil emergencies (terrorism, vandalism). Disasters may result in an inability to maintain normal conditions in the animal facility and/or an inability of personnel to reach the animal facility, thus potentially threatening the health and welfare of animals.

Critical Response Team (CRT) personnel include all BRSF personnel (animal facility manager, Attending Veterinarian, and animal technicians), Facility Management Personnel, OU Police Department, and IACUC chair, as well as all Principal Investigators with current research or teaching projects using animals.

[redacted]

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.

   Temperatures in the animal housing rooms are monitored 24 hours a day by an Edstrom Industries computer monitoring system located in room 104, the Animal Research Facility Manager's office, of the Biomedical Research Support Facility. In addition, Oakland University's Central Heat Plant (CHP) also controls and monitors the temperatures, humidity levels, and room air exchanges for all individual animal housing rooms and all other rooms within the facility 24 hours a day. The temperatures are maintained according to species requirements listed in the *Guide*. Mouse, rat, and guinea pig rooms are maintained at 68° - 79° F. The frog room is maintained at 64° - 66° F. CHP staff is alerted to problems by a computer alarm triggered by temperature deviations. Humidity for the facility is kept at 30% - 70% and is monitored 24 hours a day by Edstrom Industries' sensors placed in each individual animal housing room. CHP computers also monitor the humidity and ventilation rates for each animal housing room. Extremes in temperature and or humidity are reported to CHP for same day service. The Edstrom Industries' Data Logger monitor can be accessed to generate historical reports for temperature, humidity, air flow, light cycle function, and differential pressures, at any time for all animal housing rooms.

   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]

   The temperatures are maintained according to species requirements listed in the *Guide*. Mouse, rat, and guinea pig rooms are maintained at 68° - 79° F. The frog room is maintained at 64° - 66° F. Central Heat Plant (CHP) staff is alerted to problems by a computer alarm triggered by temperature deviations. Humidity for the facility is kept at 30% - 70%. A fluctuation of ± 5 is considered acceptable for animal holding room temperatures.

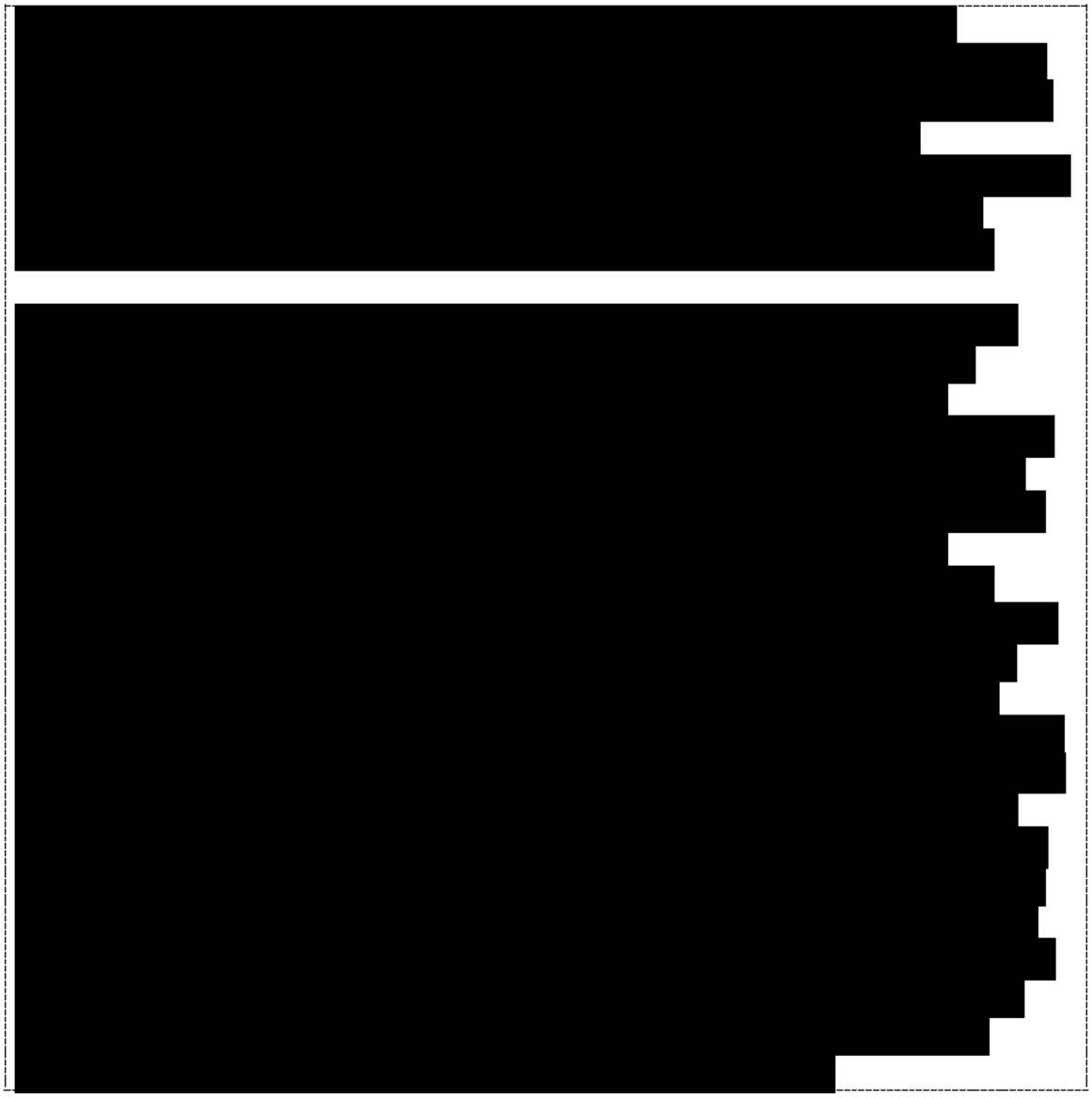
   c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their

thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Behavioral thermoregulation is enabled through social housing, the use of additional nesting material, enrichment huts, and through the use of filter top cages when/if needed.

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.



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

The BRSF does not use special primary enclosures using forced ventilation

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.

None of the animal housing rooms in the BRSF use recycled air.

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

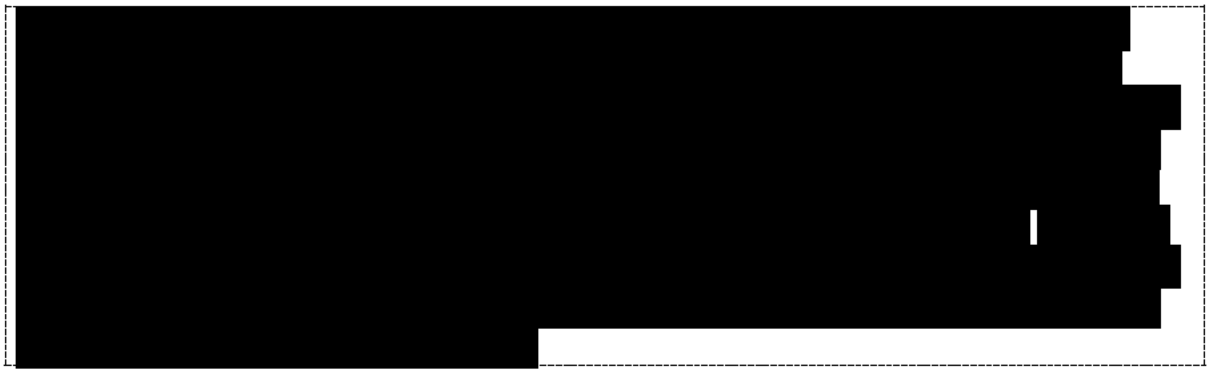
a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

Water supplied to the frogs is pre-filtered through a series of carbon filter bottles equipped with an automatic chloramine tester/sensor, and supplemented with salts to a concentration of 20 mM. An integrated water circulation/aeration/filtration system will maintain tank temperature and will ensure ideal water quality. Cleaning and maintenance of the rack system is performed as recommended by the manufacturer. Frogs and/or tadpoles may also be maintained in static housing. Freestanding tanks housed in an environmental incubator (maintains temperature and light cycle) will be utilized, and a complete change of water will be effected manually, no less than 3 times each week, generally 3-5 hours after the animals have been fed.

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).

Regardless of the housing system used, adult animal density will be no more than 1 adult frog/liter, with no more than 4 frogs/5.5 liter tank. Frogs are segregated by sex, unless breeding is desired. Tadpoles are maintained at a density of no more than 25/liter. Water quality is monitored daily by close attention to animal behavior, and by chemical assay for pH, nitrite and ammonia at least weekly.

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.



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.

References used to establish primary enclosure size and population densities include the 2011 *Guide for the Care and Use of Laboratory Animals* and the 2013 *Animal Welfare Act and Animal Welfare Regulations*. Observations of specific animals in the facility can determine densities and individual housing arrangements also, with such considerations as barbering, compatibility, breeding, etc.

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]

To date there are no IACUC approved program-wide exceptions to space requirements for animals housed at the BRSF. Space allocations are assessed, reviewed, and modified as necessary by the IACUC considering the performance indices (e.g., health, reproduction, growth, behavior, activity, and use of space) and special needs determined by the characteristics of the animal strain or species (e.g., obese, hyperactive, or arboreal animals) and experimental use (e.g., animals in long-term studies may require greater and more complex space).

At a minimum, animals are given enough space to express their natural postures and postural adjustments without touching the enclosure walls or ceiling, are able to turn around, and have ready access to food and water. In addition, there is sufficient space to comfortably rest away from areas soiled by urine and feces. Floor space taken up by food bowls, water containers, litter boxes, and enrichment devices (e.g., novel objects, toys, foraging devices) should not be considered part of the floor space.

References used to establish primary enclosure size and population densities include the 2011 Guide for the Care and Use of Laboratory Animals and the 2013 Animal Welfare Act and Animal Welfare Regulations. Observations of specific animals in the facility can determine densities and individual housing arrangements also, with such considerations as barbering, compatibility, breeding, etc.

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).

Rodents, and guinea pigs are housed on direct bedding in solid bottom see through cages. Frogs are maintained in polycarbonate tanks docked into a purpose-built modular racking system designed specifically for frog husbandry. Water supplied to the frogs is pre-filtered through a series of carbon filter bottles equipped with an automatic chloramine tester/sensor, and supplemented with salts to a concentration of 20 mM.

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).

Rodents are group housed, on contact bedding. Rodents are provided Iso-Blox enrichment squares as an adjunct environmental enrichment to the contact bedding. Iso-Blox are produced from pure hypoallergenic cotton fibers that are an FDA-approved raw material for use in human medical products and food production. Rodents are highly motivated to shred Iso-Blox to a cotton ball consistency thus producing a comfortable nest-like environment.

Additionally, Tek-Fresh shredded paper bedding is made available. Mice showing aggressive tendencies, single-housed animals, and some breeders are also provided nesting huts.

Rats housed in metabolic caging are provided food treats and nylabones to gnaw.

Guinea pigs are given alfalfa hay cubes and Timothy hay for additional nutritional environmental enrichment.

Frogs are provided plastic tubes in which to hide and rest on, with small amounts of dietary supplements such as blood worms, chopped beef heart, and chopped liver given as treats

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

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

All animals are group housed whenever possible.
Rodents and guinea pigs are housed in see-through caging allowing for visual and auditory stimulation and communication.

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 social species is the exception and justified based on experimental requirements or veterinary-related concerns about animal well-being. Protocols that require single housing of animals must provide a scientific reason to justify single housing an animal and must obtain IACUC approval to do so.
Some animals cannot be socially housed, due to their aggressive nature or for other veterinary reasons. Removing animals due to social problems such as fighting and barbering is usually done only after efforts have been made to introduce diversionary materials such as nesting material or Iso-Blox for shredding. This is done on a case-by-case basis. In these cases, single housing is limited to the minimum period necessary, and where possible, visual, auditory, olfactory, and tactile contact with compatible conspecifics is provided.

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

Every effort is made to minimize the time that animals must be isolated from others of the same species. During these periods, animals are observed minimally twice daily and returned to group or conventional housing as soon as possible. Added nesting materials and enrichment devices are provided. Single housed animals are housed in see-through caging that allows for visual and auditory communication with other animals in the room.

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.

The Attending Veterinarian and the Animal Research Facility Manager in consultation with investigators select the most appropriate bedding, nesting materials, and enrichment devices for each species to ensure and encourage natural behavior. Space allocations and exceptions to social housing of social species are reevaluated in the same manner as to provide enrichment and to accommodate what is best for the animals. These evaluations are based on species characteristics, behavior, compatibility of these animals with their cagemates, number of animals, and the goals of the housing situation, etc.
Every effort is made to minimize the time that animals must be isolated from others of the same species. During these periods, animals are observed minimally twice daily and returned to group or conventional housing as soon as possible.
Additionally, the IACUC re-examines exceptions to social housing of species semiannually during its semiannual program review.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]

Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Upon delivery and prior to the initiation of a study, all animal species used in chronic studies are subject to minimal acclimation periods. The acclimation period for rats and mice is 24 hours. The acclimation period for guinea pigs is 48 hours. The acclimation period for higher species, e.g. dogs, cats, pigs, etc. is 72 hours.
Rats used in the behavioral study are handled by research personnel at a minimum of twice a day for the first two weeks after arrival into the facility to get them accustomed to being handled during future procedures. They are then handled once a day for daily weight and condition assessment.

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).

There is no sheltered or outdoor housing associated with the BRSF

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

The animals housed in the BRSF are not exposed to weather extremes.

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

Not applicable.

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

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

Not applicable.

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

Not applicable.

iii. Describe how animals are captured.

Not applicable.

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

Food is ordered and purchased as needed from Envigo RMS, Inc. Their warehouse is located in Madison, Wisconsin. Their mill distributes species-specific lab diets, of which we feed: 2018 Rodent Diet, 8664 Rodent Diet,

2040 Guinea Pig Diet. Specially formulated diets are purchased as required by the research protocol.
Alfalfa cubes and Timothy hay is made available to the guinea pigs. These are purchased from area pet and feed stores. Freshness is verified by the manufacturer's expiration date stamped on the packaging. Fresh fruits and vegetables, if offered, are purchased from local grocery stores. These are never kept more than 5 days. Frogs are fed 3 times each week, using an appropriate and proven well balanced commercial diet, such as Trout Chow Pellets, Nasco Frog Brittle and/or Rangen soft-moist salmon diet. Tadpoles are filter feeders and begin to feed on suspended food particles at about 10 days of age. Tadpoles aged 8 days and older are fed daily by application of commercial strained baby food (green beans or peas), or commercial powdered tadpole food (Nasco). Tadpoles are only fed when the "cloudiness" from the previous batch of food has been consumed.

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

Only excess unopened bags of food are stored in the facility's assigned ground level Receiving/Dock area room G003 of the Mathematics and Science Center (MSC). Bags of food are stacked on metal shelving units and separated according to type of food. When new shipments arrive, stock is rotated so that product with an earlier milling date is placed at the top so that it is picked up and used first, and the product with a later mill date is placed at the bottom. Staff are required to verify mill dates and expiration dates before taking any bags of food from the storage area. Two live traps are placed at the dock door and insect sticky traps are placed in the room. The live traps are checked daily. The food is stored at ambient room temperatures. We have had no evidence of or problems with infestation of vermin in this space.

[redacted] Unopened bags of food are stacked on metal shelving units and separated according to type of food. When food is brought in, to be stored in this room, bags are re-arranged and rotated so that the oldest food, with the latest mill date, is placed at the top of the stack to insure it being utilized first. Staff are required to verify mill dates and expiration dates before opening any bags of food. Opened food is placed in large plastic bags (trash bags) that line

the inside of large rubber storage bins, equipped with lids, and on casters. Food is stored at ambient room temperatures.

Temperature and Humidity levels are monitored and recorded in both of these spaces and records are kept in the BRSF Operations Monitoring and Maintenance Schedules Notebook.

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).

There is no specific area assigned to food preparation. Presently all food being fed does not require any kind of preparation. There are counter/sink areas located in several support and procedure rooms throughout the facility that can be utilized for this purpose if needed.

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

Rodents are fed ad lib and food is provided in stainless steel hanging feeders, or in stainless steel wire cage lids with self-contained feeders. Food is added to mouse feeders as needed. Rat feeders are topped off at the time the cages are changed, and then again midweek.

Guinea pigs are fed ad lib and food is provided in stainless steel hanging feeders or ceramic crocks. The food in the feeders is leveled off once a day. Additional food is added to the feeders when the levels are low. The food is completely changed out if it is soiled or contaminated.

Adult frogs are fed 3 times each week, using an appropriate and proven well balanced diet, such as Trout Chow Pellets, Nasco Frog Brittle and/or Rangen soft-moist salmon diet. Tadpoles are filter feeders and begin to feed on suspended food particles at about 10 days of age. Tadpoles aged 8 days and older will be fed daily by application of commercial strained baby food (green beans or peas), or commercial powdered tadpole food (Nasco). Tadpoles will only be fed when the "cloudiness" from the previous batch of food has been consumed.

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

All food is purchased from a reputable company with guaranteed analysis, thus assuring nutritional quality. If specially formulated foods are requested and ordered for investigators, BRSF staff check with feed manufacturers to determine storage requirements and expiration dates. Damaged or short-dated bags are rejected upon delivery. Unopened bags of food are rotated in the food storage rooms to insure freshness. All animal diets are disposed of six months after the mill date. The plastic bags that line the food storage bins are changed at the time new food is placed in the container. The large rubber storage bins are cleaned and disinfected by hand spraying them with LABSAN 256, followed by a hot water rinse, once every three months. Labels are affixed to all food storage containers to track, type, expiration date, and date the container was disinfected. BRSF employs the use of sticky insect traps in the food storage spaces and these are monitored monthly and replaced as needed. We have had no evidence of or problems with infestation of vermin in the spaces where food is stored.

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).

All water is supplied by the City of Detroit Water Department which meets all city, state, and Environmental Protection Agency (EPA) standards. The water is further treated with the addition of chlorine. The BRSF is equipped with the Edstrom Industries, Inc. Automated Watering Equipment. Chlorinated water is introduced into the water supply lines by placing it in a Central Proportioner reservoir holding tank. A chlorine solution is made up with household strength liquid bleach and water as per the manufacturers' recommendations. A standard dilution ratio, recommended by Edstrom Industries, Inc., is used to determine the concentration of bleach to water. A measured or proportioned amount of this chlorinated water is then pumped from the reservoir holding tank into the animals' drinking water supply lines using the Edstrom equipment. The water supply lines are automatically flushed twice daily. The facility is also equipped with four Pressure Reducing Flush Stations along the water supply line route. Filters at each of the four Pressure Reducing Stations are changed every three months or more often if needed. The BRSF uses the HACH Company's Chlorine Test Kit Model CN-2254-01 to monitor the ppm (parts per million) of chlorine to water.

- Chlorine level tests of the animals' drinking water, taken at one of the four Pressure Reducing Flush Stations, are performed once a month or more often if the need arises.
- Additional chlorine level tests are performed once a month at the Central Proportioner.

- Test results are recorded on the BRSF's Chlorine Level Monitoring Log sheet.
- Adjustments to the Edstrom Automated Watering Equipment are made if the resulting ppm is out of the normal range.

The rodents and guinea pigs that do not have caging docked on an automatic watering rack are placed on water bottles with sipper tubes. Animals are observed to determine proper usage of watering devices.

Frogs, tadpoles, do not drink; instead, they absorb water through a highly permeable, specialized area of skin in the pelvic region. The skin is also largely responsible for respiration via its outer surface. Water supplied to the frogs is pre-filtered through a series of carbon filter bottles equipped with an automatic chloramine tester/sensor, and supplemented with salts to a concentration of 20 mM. An integrated water circulation/aeration/filtration system maintains the tank temperature and ensures ideal water quality.

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

Water quality is further monitored for microbial contaminants.

- Once a month an AquaSnap Total™ ATP Test for water samples is run on a sample of the animals' drinking water taken at one of the four Pressure Reducing Flush Stations.

- Once a month an AquaSnap Total™ ATP Test for water samples is run for all animal housing rooms in which automatic watering racks are in use. Samples are taken from a representative automatic watering rack and from a recoil hose drop.

- Test results using the AquaSnap Total™ are recorded and logged in the *BRSF Operations Monitoring and Maintenance* Schedules notebook.

The City of Detroit water supply meets all city, state, and EPA standards. Chlorine level tests of the animals' drinking water are performed once a month or more often if the need arises. Water bottles are visually examined for cleanliness and water clarity at the time they are placed on the animal cage, and at a minimum thereafter of once a day.

Water supplied to the frogs is pre-filtered through a series of carbon filter bottles equipped with an automatic chloramine tester/sensor, and supplemented with salts to a concentration of 20 mM. An integrated water circulation/aeration/filtration system maintains the tank temperature and ensures ideal water quality.

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

All water is supplied by the City of Detroit Water Department which meets all city, state, and EPA standards. The water is further treated with the addition of chlorine. The BRSF is equipped with the Edstrom Industries, Inc. Automated Watering Equipment. Chlorinated water is introduced into the water supply lines by placing it in a Central Proportioner reservoir holding tank. A chlorine solution is made up with household strength liquid bleach and water. A standard dilution ratio, recommended by Edstrom Industries, Inc., is used to determine the concentration of bleach to water. A measured or proportioned amount of this chlorinated water is then pumped from the reservoir holding tank into the animals' drinking water supply lines using the Edstrom equipment. The water supply lines are automatically flushed twice daily. The facility is also equipped with four Pressure Reducing Flush Stations along the water supply line route. Filters at each of the four Pressure Reducing Stations are changed every three months or more often if needed. The BRSF uses the HACH Company's Chlorine Test Kit Model CN-2254-01 to monitor the ppm (parts per million) of chlorine to water.

- Chlorine level tests of the animals' drinking water, taken at one of the four Pressure Reducing Flush Stations, are performed once a month or more often if the need arises.
- Additional chlorine level tests are performed once a month at the Central Proportioner.
- Test results are recorded on the BRSF's Chlorine Level Monitoring Log sheet.
- Adjustments to the Edstrom Automated Watering Equipment are made if the resulting ppm is out of the normal range.

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

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

A 2:1 mixture of Envigo RMS, Inc., Tek-Fresh #7099 paper bedding, and their Pelleted Paper Bedding #7084, is used as direct bedding for guinea pigs. Teklad Corncob Bedding #7097 is used as direct bedding for mice and rats. Teklad irradiated 6" X 10" Iso-Blox pads are used in all micro-isolator cages housing NSG scid mice. Bedding is selected based upon needs for absorbency and comfort of the animals.

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

Only, excess unopened bags of bedding, are stored in the facility's assigned ground level Receiving/Dock area room #G003 of the

Mathematics and Science Center (MSC). Bags of bedding are stacked on metal shelving units and separated according to type of bedding. When new shipments of bedding arrive, the bags are rearranged and rotated so that the oldest bedding is placed at the top of the stack to insure they are utilized first. The bedding is stored at ambient room temperatures. BRSF staff employs the use and routine monitoring of insect sticky traps in this space. Two live traps are placed at the dock door and insect sticky traps are placed in the room. The live traps are checked daily. We have had no evidence of or problems with infestation of vermin in this space.

When bedding is brought up from the Receiving/Dock area, it is kept in the Feed and Bedding Room #137, on the main floor of the facility. Unopened bags of bedding are stacked on metal shelving units and separated according to type of bedding. When bedding is brought in, to be stored in this room, it is re-arranged and rotated so that the oldest bags are placed at the top of the stack to insure it is utilized first. Opened bags are stored in large plastic storage bins, with lids, and on casters. Insect sticky traps are strategically placed in the room. We have had no evidence of or problems with insect infestation or vermin in this space.

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

All bedding is purchased from reputable companies with guaranteed analysis, thus assuring quality. Damaged or short-dated bags are rejected upon delivery. Unopened bags of bedding are rotated in the storage rooms so that the oldest food is placed at the top of the stack to insure it being utilized first. The large rubber storage bins are cleaned and disinfected by hand spraying them with LABSAN 256, followed by a hot water rinse, once every three months. Labels are affixed to all bedding storage containers to track, type, date bedding is opened and placed in the container, and date the container was disinfected. Insect sticky traps are employed in the Feed and Bedding Room 137 of the facility and also in the North Dock Feed and Bedding Room G016 in the basement. These traps are replaced every 3 months or more often if necessary. We have had no evidence of or problems with insect infestation or vermin in either of the spaces where feed and bedding is stored.

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.

The Biomedical Research Support Facility does not have an assigned motorized vehicle.

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.).

[redacted]

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.

Rodents – Direct bedding in solid bottom, shoebox cages, mice and rats is changed once per week; Guinea Pigs – Direct bedding in solid bottom cages, is changed once a week. A bedding change is provided more frequently as needed.

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

Rats – One IACUC approved protocol involving rats in a behavioral study has rat caging, bedding, and feeders, changed once every two weeks, and the automatic watering rack upon which the cages are docked is sanitized once a month to minimize disturbance and variables in the behavioral study.

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

Dirty cages enter the dirty cage processing area from the perimeter corridor. All used caging materials, accessories, and equipment; enter this room for prepping before entering the cage and rack washer or the tunnel washer.

Dirty cages are taken to the Dirty Cage Processing room #147. The soiled bedding is removed from the cages using a negative flow bedding disposal unit called a bioBubble® and bagged for disposal. Rodent cages containing infectious bedding are autoclaved for decontamination prior to bedding disposal and routine cage washing. Clean cages are

bedded in Clean Cage Processing room 138/139. No cages are dumped or filled with bedding in animal housing rooms.

Clean cages are bedded either in the Clean Cage Processing room #138/139, or the Feed/Bedding Storage room. These rooms are adjacent to each other. The bedding is stored in large rubber storage bins which are outfitted with wheeled canisters making it more convenient to move the bins between the two rooms as needed. When a small number of cages need to be bedded it is done in the Feed/Bedding Storage. Large numbers of cages are bedded in Clean Cage Processing as space allows.

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.

Rats – One IACUC approved protocol involving rats in a behavioral study has rat caging, bedding, and feeders, changed once every two weeks, and the automatic watering rack upon which the cages are docked is sanitized once a month to minimize disturbance and variables in the behavioral study.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

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

The Rack Washer is Getinge Model 4070 Cage & Rack Washer. All cage racks, are sanitized using Cycle 1.
Cycle 1 is as follows:
- Prewash – time 240 seconds, temperature 50°F, temperature not guaranteed.
- Wash 1 – alkaline wash, time 240 seconds, temperature 150°F, soak 30 seconds, temperature is guaranteed, the dispenser is on.
- Rinse 1 – time 90 seconds, temperature 160°F, temperature not guaranteed.
- Wash 2 – acid wash, time 240 seconds, temperature 150°F,

soak 30 seconds, temperature is guaranteed, the dispenser is on.
- Rinse 2 – time 90 seconds, temperature 160°F, temperature not guaranteed.
- Rinse 3 – time 180 seconds, final rinse temperature 180° F
- Exhaust – time 30 seconds.

Washing cycle parameters are recorded and printed out by the mechanical washing equipment. In addition to this the BRSF employs the use of Getinge Thermolabel Temperature-Sensitive Tape to monitor the temperature of the water when sanitizing animal cage racks, equipment, and accessories, through the Rack Washer on a weekly basis. All items removed from the cage wash are visibly inspected for cleanliness. Once a month an UltraSnap™ ATP Test Swab to test for bacterial contamination analysis is run on a processed rack as a representational sampling.

All solid bottom cages, cages lids, feeders, water bottles, sipper tubes, cage card holders, and miscellaneous caging accessories, are sanitized in the Tunnel, Cage & Utensil Washer. This washer is of the MTP Custom Machinery Corporation product line for Getinge Castle, Model 2224 Tunnel, Cage & Utensil Washer.

The Tunnel Washer is run on a continuous cycle. The length of the cycle is dependent upon how long the machine is on and how many items are being run through it. Dirty items are placed on a stainless steel conveyor belt at the loading end of the machine located in room #147 Dirty Cage Processing, and unloaded at the clean end located in room #138 Clean Cage Processing using Cycle
Cycle 1 is as follows:
- Wash 1 – acid wash, temperature 140°F, temperature is guaranteed.
- Rinse 1 – temperature 150°F, temperature is guaranteed.
- Final Rinse – temperature 180°F
- Hot Air Dry

Washing cycle parameters are recorded and printed out by the mechanical washing equipment. Microbiological monitoring is performed on a monthly basis on the items that have gone through a Tunnel Washer cycle using an UltraSnap™ ATP Test Swab to test for bacterial contamination analysis is run on a processed rack as a representational sampling to analyze the effectiveness of sanitation. The UltraSnap™ ATP Test Swab detects ATP (adenosine triphosphate) an organic molecule that is used by living cells as their main source of energy. ATP is associated with microorganisms and

organic product residues present on surfaces. All items removed from the cage wash are visibly inspected for cleanliness.

b) Describe preventive maintenance programs for mechanical washers.

The BRSF contracts with a commercial vendor for a service maintenance agreement to service the Rack Washer, the Tunnel Washer, and the two pass-through autoclaves. The contract is renewed on an annual basis. Services include, but are not limited to, lubrication, personnel instruction, and technical adjustments. All parts necessary for maintenance and/or repairs of equipment are included in the agreement. The only parts excluded are structural components, welding, electronic boards, pumps and motors. Service calls are at no charge. Preventive maintenance on the machinery is performed quarterly.
Another commercial vendor provides annual preventive maintenance on the chemical feed pumps to the Rack Washer and Tunnel Washer to ensure that the chemicals used are being delivered properly and in the correct amount.
The university's Facility Management personnel are available, and have serviced the equipment in emergency situations.

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

i. Soiled bedding and refuse.

All soiled bedding is bagged and taken out to a garbage dumpster located in the service court and placed in a trash dumpster for weekly pick up by a commercial waste hauling company hired by the university. Solid refuse is collected daily from waste bins throughout the facility, placed in plastic garbage bags, and taken to the service court and placed in a trash dumpster for weekly pick up.

All biologically contaminated bedding and refuse is kept separate from all other waste and collected in red biological waste bags. These bags are then autoclaved for decontamination before disposal. Standard operating procedures are followed for STZ contaminated bedding according to the recommendations of EH&S and the Biosafety Committee oversight. STZ contaminated bedding is placed in red biohazard waste bags and stored in the facility freezer for disposal using the university contracted licensed medical waste hauler.

All hazardous waste, infectious, toxic, etc., is managed according to the Oakland University Hazardous Waste Management Guidance Manual. All hazardous waste generating departments on campus play an active role in hazardous waste minimization. Hazardous waste is picked up by EH&S for disposal through the university contracted licensed medical waste hauler.

The Radiation Safety Committee reviews and approves all protocols involving the use of animals and radioactive substances before a project will receive full IACUC approval. Radioactive material (including machinery producing ionizing radiation) can only be used by authorized Oakland University permit holders or under the supervision of a permit holder. User permits are issued by the RSC. User permits are issued to full-time OU faculty members or principal investigators only.

Oakland University's Office of Environmental Health and Safety manages the disposal of radioactive and mixed waste through Oakland University's Radiation Safety Program. All radioactive waste handling procedures are conducted in compliance with applicable Nuclear Regulatory Commission and Michigan Department of Environmental Quality Regulations. Radioactive waste which has half-lives that allow for ten-half-life decay within 3 years will be temporarily stored for decay, surveyed and then disposed by drain or the regular trash. Radioactive mixed waste or radioactive liquid industrial waste is transferred to a licensed radioactive waste treatment storage disposal facility.

Sharps canisters are provided in all procedure rooms. Once canisters are full they are autoclaved for decontamination and picked up by EH&S for disposal through the university contracted licensed medical waste hauler.

All uncontaminated glass items too large to be placed in a sharps canister are wrapped in heavy paper and placed in a container identified as glass waste and disposed of by the university's custodial service personnel.

ii. Animal carcasses.

Animal carcasses are double bagged in plastic garbage bags and placed in large covered garbage bins and stored in the Necropsy room #112A in the facility. At the end of the day the carcasses are taken to a locked waste holding room in the south receiving dock of the facility and placed in a commercial chest freezer. When the freezer is filled, an animal disposal service picks up the carcasses for incineration. The freezer is checked weekly for proper operation.

All transgenic animal carcasses and animal carcasses identified as biohazard contaminated are double bagged and placed in red biohazard

waste bags and stored in the commercial chest freezer. Contaminated carcasses are picked up monthly by EH&S for disposal through the university contracted licensed medical waste hauler.

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).

Oakland University contracts with the pest control company called, Rose Pest Solutions to service the facility once a month. Rose Pest Solutions monitors the administrative offices of the facility, their corridors, and the entrances and exits to the facility. The BRSF staff monitors spaces throughout the animal facility that are not serviced by Rose Pest Solutions, using insect sticky traps to control minor problems with an occasional insect. These sticky traps do not contain any chemicals or pesticides and are checked monthly by BRSF staff and replaced as needed. Pest control records are kept in the BRSF Operations Monitoring and Maintenance Schedules Notebook. The sticky traps are not used in any of the animal housing rooms, surgical support rooms, or corridors. Rose Pest Solutions does not service any of these areas. There have been no reported problems with insects or vermin in the facility.

Live traps are employed in the basement dock area at the garage door entrances where feed and bedding is stored. These live traps are checked daily to ensure the humane capture of vermin. No vermin have been captured in these traps since being put into use six years ago.

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.

The use of natural predators or guard animals are not used for pest and predator control.

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

The use of insecticides is not employed in this facility.

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.

At least one member of the BRSF staff is assigned to work holidays and weekends to provide basic husbandry care and observation of the animals. Cases of emergency closure of the university at least one of the staff come into the facility to check the animals. In instances where a staff member is unable to come in during an emergency closure arrangements can be made with the campus police department for one of their officers to monitor the animals. To date we have never had to rely on this arrangement.

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

The BRSF staff qualifications are listed in section 1.A.2.2.ii. above.
To date we have never had to rely on campus police officers to monitor the animals in emergency closure situations. If this does occur then OU Police will contact the BRSF Manager and perform the animal monitoring under the direction of the BRSF Manager.

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

If any animal related veterinary medical problems arise, the BRSF staff contacts the Attending Veterinarian (on call 24/7/365) and the principal investigator. In the event the Attending Veterinarian is unavailable the backup veterinarian is contacted. Non-medical problems are brought to the attention of the Animal Research Facility Manager or the Research Laboratory Veterinary Technicians, who are available by phone. In the event of an emergency after hours, the campus police have a telephone list of the Attending Veterinarian and the BRSF staff personnel to contact.

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

a. Identification

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

Cage cards or charts identify all animals. Rodents, guinea pigs, have their cage cards affixed directly to their caging. All cage cards are color coded for species identification; i. e. yellow for mice, gold for rats, white for guinea pigs, etc. The information recorded on cage cards includes: animal ID number and unique physical characteristic or coloration if applicable, species, sex, strain, age and weight, protocol number, investigator name and phone number, office number and building location, date of arrival, number of animals in the cage if

applicable, and the name of the vendor. Certain investigators also ear tag or ear punch their rodents, or tattoo them, using the tail or toe pad, for individual identification.

b. Breeding, Genetics, and Nomenclature

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

Investigators are encouraged to familiarize themselves with appropriate animal models using literature searches and references gathered when developing their protocol. From their experience and/or research, they are responsible to select the exact genetic characterization and definition of rodent animal models necessary to insure consistency and reproducibility of their research. Using appropriate standardized nomenclature is critical whether inbred, outbred, or transgenic animals, are involved. Similarly monitoring genetic purity and maintaining genetic precision of animal models is important. During the veterinary consult, the Attending Veterinarian will review the Investigator's choice of animal model and may make alternative suggestions. The final determination on the appropriateness of the animal model used lies with the IACUC.

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.

Suggested resources for investigators for the use of standard nomenclature are made available in Oakland University's Training and Information Manual Animal Care and Use and in the Application to Use Vertebrate Animals in Research, Teaching or Testing.
Investigators are also advised to use the online resources available through the commercial animal vendor websites such as, Jackson Laboratory, Charles River, Envigo Research Models, etc.

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

Genetic authenticity is monitored by genotyping progeny when using inbred animals. Progeny are genotyped at the time of weaning or when they are separated according to sex. Individual PIs keep their own breeding records for this purpose.

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."

When specialized genotypic animals are used, the IACUC requires the PI to provide verification of any unique phenotypic, physiological, or behavioral exceptions or needs. Additionally, the Attending Veterinarian reviews this information as part of the standard IACUC application review process. The BRSF staff observes all animals, including genotypically modified animals, for any deviations from normal expected specie parameters (e.g., longevity). In accordance with the IACUC SOP – Guidance on Prompt Reporting of Unanticipated Problems, all unexpected behaviors or results are reported to the Attending Veterinarian and, if appropriate, to 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.).

Evaluation of animal quality begins with an assessment of the program of health and veterinary care and historical health records maintained by our vendors and shipped with the animals. Animals procured from commercial or research institutions have their health surveillance records verified and approved prior to shipment, and shipping and receipt is coordinated by the Attending Veterinarian and the BRSF Manager. A licensed veterinary technician assesses the condition of each animal upon arrival.

Rodents are purchased from Envigo RMS, Inc., Indianapolis, Indiana, Charles River Laboratories, Wilmington, Massachusetts, and The Jackson Laboratory, Bar Harbor, Maine. These vendors offer an extensive genotype and disease-monitoring programs that guarantee the delivery of healthy animals.

Guinea Pigs are purchased from Kuiper Rabbit Ranch, Gary, Indiana, and Hilltop Lab Animals, Inc., Scottsdale, Pennsylvania. Only purpose-bred guinea pigs are used.

Frogs are purchased from xenopusone.com, Dexter, Michigan.

2. Transportation of Animals

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

The supplier or the supplier's agent brings all animals directly to the university. Depending on the supplier's location, animals may arrive via truck or van, or the animals may travel by air and then be transported to our facility by van from the airport via pre-arranged accommodations (rodents). Rodents may be transported to researchers' labs within closed, ventilated containers. Animals are not transported outside of the building complex. When approved transportation of animals (rats and mice) from the BRSF to investigators' laboratories in Dodge Hall for the purpose of imaging, or euthanasia and immediate tissue removal is required, the animals are transported in ventilated containers directly to the researcher's lab with minimum exposure to common hallways. The BRSF does not own a vehicle for the transportation of animals.

Adult Xenopus are typically shipped in sealed buckets with moist foam cubes or damp moss to prevent desiccation and to cushion any bumps or shocks. Shipment containers also provide appropriate temperature, space, oxygen, separation and clean water. Frogs arriving in water will be allowed to adjust to the new enclosure's temperature. The shipment water will be kept with the new arrivals and gradually be replaced by slow dilution over several days with facility water to avoid "shock" to the new animals. The person providing care will always tend first to established healthy collections and breeding colonies, and new arrivals will be handled last. Separate holding tanks and separate handling equipment (nets, scoops, etc.) are utilized for the quarantined animals.

One PI does have IACUC approval to transport singular mice in IACUC approved shipping containers to be directly delivered by his personal, temperature controlled vehicle to a collaborating researchers' laboratory at a nearby university. Upon arrival, all animals are properly handled following the Oakland University approved protocol and the receiving university's IACUC approved protocol. A Memorandum of Understanding is also in place. The animals are immediately euthanized for tissue for experiments. All animals euthanized for the research are disposed of at the collaborator's facility.

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.

All animals received must go through a required acclimation/observation period before being used in a research study. All rodents and are checked for signs of obvious illness by a licensed veterinary technician on the day they arrive. Those with evidence of disease are isolated or euthanized as determined appropriate. Additionally, the health status of the rodent colonies in the BRSF facility is monitored through the use of a viral screening program using "sentinel" animals. Designated sentinel mice and rats are placed in appropriate colony rooms every 4 months. Mini profiles are performed twice yearly with complete tracking profiles on mice and rats performed once a year. Additional rodent colony screening is performed upon PI request. A necropsy is performed on all animals that die unexpectedly.. A licensed veterinary technician or the investigator performs the necropsies. Necropsies are conducted in a designated room equipped with a stainless steel, downdraft table. Histopathology examinations are done when indicated by a commercial laboratory.
All guinea pigs, are checked for signs of obvious illness by a licensed veterinary technician on the day they arrive. Those with evidence of disease or injury are rejected and replaced by the vendor. These animal species are weighed and given individual physical exams within 24 hours of arrival.
For Xenopus, the person providing care will always tend first to established healthy collections and breeding colonies, and new arrivals will be handled last. Separate holding tanks and separate handling equipment (nets, scoops, etc.) will be utilized for the quarantined animals. Caretakers will conduct frequent hand washings and glove changes between cages of different shipments and between individual animals.

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

All animals are observed and evaluated by BRSF and/or research staff daily. If an animal or group of animals are confirmed or suspected to have an infectious agent, the BRSF manager and Attending Veterinarian are consulted, and the PI is informed and/or consulted. Animals may be euthanized if deemed appropriate. If treatment is decided upon, the animal is isolated whenever possible, and appropriate measures are then implemented, and may include: prohibition of additional animals being introduced into the colony; prevention of animals transferred out of the colony; husbandry scheduling and sequencing to address infected animals last; posting of additional measures and/or husbandry procedures and infection control procedures on housing doors and provision of appropriate personal materials/gear for research personnel. Individual animals may be isolated and treated or managed, if deemed appropriate.

A necropsy is performed on all animals that die unexpectedly. A licensed veterinary technician or the investigator performs the necropsies. Necropsies are conducted in a designated room equipped with a stainless steel, downdraft table. Histopathology examinations are done when indicated by a commercial laboratory.

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

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

Evaluation of colony and/or individual animal health status, as provided by the supplier, is used to determine initial housing or isolation procedures after the initial examination and acclimation period are observed.

All animals received must go through a required acclimation/observation period before being used in a research study. The acclimation period for rodents is 24 hours, for guinea pigs is 48 hours. All rodents are checked for signs of obvious illness by a licensed veterinary technician on the day they arrive. Those with evidence of disease are isolated or euthanized as determined appropriate. All guinea pigs and are checked for signs of obvious illness by a licensed veterinary technician on the day they arrive. Those with evidence of disease or injury are rejected and replaced by the vendor. Guinea pigs are weighed and given individual physical exams within 24 hours of arrival. Separate holding tanks and separate handling equipment (nets, scoops, etc.) are utilized for the quarantined frogs. Caretakers will conduct frequent hand washings and glove changes between cages of different shipments and between individual animals.

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.

Separate caging and housing is available should an animal require prolonged isolation or quarantine, though this has not yet occurred in our facility. Additionally, micro-isolator caging is available for rodents if deemed appropriate.

Animals from all sources are housed separately by species and by vendor source as space allows. Providing health status data from the supplier is supportive, newly arriving animals may be placed in the same room with like species upon arrival. Animals are observed for the appropriate period to assure adequate acclimation.

Micro-isolator caging is an available option for rodents arriving from a non-commercial vendor source (a research collaborator at another research

institution) or if health status differs between new and previously-housed animals.

All new frogs will be quarantined on arrival, using separate cages for new animals. New animals will be quarantined at least 7-10 days and examined daily for activity level, skin discoloration, skin ulcerations, petechial (pinpoint) hemorrhages on the legs, abdominal swelling or any other unusual changes. Preventative treatments for newly shipped animals may include placing frogs in a 0.6% calcium hypochlorite solution (or a 0.06% sodium chloride solution) to reduce the growth of Aeromonas hydrophilia and occurrence of "Red Leg".

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

All animals received must go through a required acclimation/observation period before being used in a research study. The acclimation period for rodents and frogs is 24 hours, for guinea pigs, is 48 hours.
After evaluation by the licensed veterinary technicians, animals that may not have fully acclimated are given special accommodations such as unique feeding and watering procedures until they are stabilized and able to enter into the study.

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.

All animals are appropriately separated by species and health status. Rodents from more than one source are housed together in animal housing rooms due to space and housing limitations. There is no mixing of species in the facility. Animals exhibiting signs of illness are examined, and diagnostics and treatment are instituted as appropriate. All potentially infectious animals are isolated if not euthanized.

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

Multiple species are not housed in the same room, area, or enclosure.

c. Describe isolation procedures and related facilities for animals.

All animals are appropriately separated by species, and health status. Rodents from more than one source may be housed together in animal housing rooms

due to space and housing limitations, after health status compatibility has been determined. There is no mixing of species in the facility. Animals exhibiting signs of illness are examined, and diagnostics and treatment are instituted as appropriate. All potentially infectious animals are isolated if not euthanized.

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

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

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

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

All animals are observed daily by the licensed veterinary technicians and research staff. Research staff are trained to recognize abnormalities in such things as behavior, feces production, feeding habits, etc. The licensed veterinary technicians are trained in recognizing the signs of general illness or common infectious diseases affecting specific species and are experienced in performing daily examinations, medical treatments, and routine care such as nail trimmings, ear cleaning, etc. Guinea pigs' weights are checked upon arrival and then once a month at the time of their complete physical exams, or more often if warranted. Temperatures are taken as warranted. The research staff and technicians report abnormalities directly to the Attending Veterinarian via phone, email, or text message. The veterinary technicians or the Attending Veterinarian notes all significant behavioral and physical changes on the animals' general health records. All issues related to the health of the animals are dealt with promptly. Physical examinations are performed on animals once a health issue is reported. If the animals have any wounds they are assessed and treated as they are reported. Animals deemed in need of immediate pain relief or relief from distress are treated immediately or euthanized.

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

Research staff and veterinary technicians report any symptomatic animals directly to the Attending Veterinarian. Direction of treatment is based upon physical examination and observation. Control of treatment is directed by the Attending Veterinarian, either orally or written in the medical record, after discussion with the investigator and administered primarily by the veterinary technicians or by the principal investigator's trained research staff. If the animal

is in discomfort, the Attending Veterinarian and investigator are notified immediately and appropriate action is taken at once. All health issues and subsequent treatment information is documented on the animals' cage cards or recorded in their individual animal medical record.

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.

Rodents – The health status of the rodent colonies in the BRSF facility are monitored through the use of a viral screening program using "sentinel" animals. Designated sentinel mice and rats are placed in appropriate colony rooms every 4 months. Mini profiles are performed twice yearly with complete tracking profiles on mice and rats performed once a year. Additional rodent colony screening is performed upon PI request.
Guinea pigs – A physical exam is given monthly which includes weighing and looking for malocclusions, impactions, checking the eyes, performing necessary nail trims, cleaning the ears, and checking overall hair coat and condition.
Frogs and amphibians are observed daily for signs of disease or distress.

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.

BRSF staff are assigned as needed to work all holidays, weekends, and emergency closures to provide basic husbandry care and observation of the animals. Principal Investigators that house amphibians in their labs have responsible care staff that is required to care for the animals on holidays and weekends in addition to regular work hours. All animal care personnel are required to document and record their daily findings and activities on animal room maintenance charts.

If any medical problems arise, the BRSF staff contacts the Attending Veterinarian (on call 24/7/365) and the investigator.

In the event the Attending Veterinarian is or will be unavailable, prior arrangements have been made with the emergency backup veterinarian who is then contacted. All medical/health problems are brought to the attention of the Animal Research Facility Manager or a Research Laboratory Veterinary Technician, who are available by phone 24/7.

In the event of an emergency after hours, the campus police have a telephone list of BRSF staff personnel to call.

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

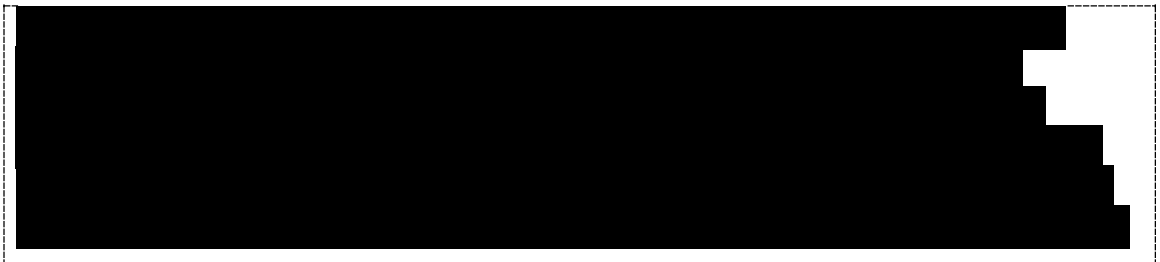
The Institution, the IO, and the IACUC, have granted the Attending Veterinarian sufficient authority and resources to manage the program of veterinary care: to have access to all animals, to treat an animal and institute appropriate measures to relieve severe pain or distress, to remove them from the experiment, or perform euthanasia. In fulfilling these duties in the research environment, the Attending Veterinarian interacts collaboratively with the research team (e.g., the Principal Investigator) when making critical decisions regarding animal health and welfare. The Attending Veterinarian has direct program authority and responsibility for the Institution's animal care and use program.

Emergency care is provided either personally or via licensed veterinary technicians under the Attending Veterinarian's direction. Specific instructions may be communicated by such means as telephone, fax, email, or prior written instructions and guidelines.

Research staff and veterinary technicians report any symptomatic animals directly to the Attending Veterinarian. Direction of treatment is based upon physical examination and observation. Control of treatment is directed by the Attending Veterinarian, either orally or written in the medical record, after discussion with the investigator and administered primarily by the veterinary technicians. If the animal is in discomfort, the Attending Veterinarian and investigator are notified immediately and appropriate action is taken at once. All information is recorded in the medical record.

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.



Animal records include: initial examination and arrival information, daily reports of physical and behavioral status, if abnormal, diagnostic test results, medical treatments, detailed anesthetic information, and procedural records.

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 maintenance of medical records is primarily the responsibility of the licensed veterinary technicians and includes all management and/or treatment procedures assigned by the Attending Veterinarian. All health records are kept for a minimum of three years after the animals' disposition or death. All medical records are made available to the Attending Veterinarian, the IACUC, and principal investigators for review at any time.

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

In the event of direct observation or examination of animals warranting specific medical or husbandry intervention, the Attending Veterinarian communicates instructions directly with the BRSF staff and provides written instructions in the medical record. If direction is given via email communications with the facility manager, the email communication is kept as written verification of instructions and any follow-up, if warranted.

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

a. In-house diagnostic laboratory capabilities.

The BRSF can perform in-house microscopic examinations such as skin scrapings, ear swabs, etc.

b. Commercially provided diagnostic laboratory services.

Histopathology samples may be processed using a commercial veterinary laboratory. Hematology, chemistry profiles, bacteriological cultures and sensitivities, and fungal cultures, are rarely performed. If needed, a commercial veterinary laboratory is used. Charles Rivers provides diagnostic laboratory services for the rodent health surveillance program.

c. Necropsy facilities and histopathology capabilities.

A necropsy is performed on all animals that die unexpectedly. A licensed veterinary technician or the investigator performs the necropsies. Necropsies

are conducted in a designated room equipped with a stainless steel, downdraft table. Histopathology examinations are done when indicated by a commercial laboratory.

d. Radiology and other imaging capabilities.

The BRSF currently does not possess the capability to perform radiograph

5. Drug Storage and Control

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

The Laboratory Compliance Manager, with the Office of EH&S, is responsible for overseeing and approving the ordering of all controlled substances on campus. The PIs using controlled substances and non-controlled drugs are responsible for their own DEA and Michigan State Controlled Substance licenses and storage of these items in their own individual labs or offices.
For drugs ordered for use by BRSF staff, when new shipments of drugs arrive, stock is rotated so that those with the longest expiration date are moved to the back. In addition, the dates on drugs or supplies are checked before every use to verify that there are no expired drugs or supplies still in stock.
[redacted]

b. Describe record keeping procedures for controlled substances.

The licensed veterinary technicians maintain records on all controlled substances. A Controlled Substance Log is maintained by the licensed veterinary technicians for each of the drugs. Each vial's content is kept track of with identifying information and amounts used recorded. Controlled substances and the amounts used, are recorded for each animal as part of the surgical record and kept with the animal's medical record. An annual inventory/audit of all controlled substances is completed by the BRSF Manager and the Laboratory Compliance Manager and submitted to the State of Michigan.

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.

Pre-surgical planning occurs for all aspects of the surgery in several stages, depending on the specific species, equipment and procedures being performed, as well as the anticipated outcome for the animals. Planning begins with consultation with the facility manager prior to protocol submission, and includes personnel, procedures to be performed, supplies, location, and expected pre- and post-operative care. Planning continues with consultation with the Attending Veterinarian for the same criteria prior to protocol submission, and then again with the Attending Veterinarian during protocol review (if needed). Detailed planning occurs with the facility manager and Attending Veterinarian, if needed, once the protocol has received IACUC approval and prior to initiation of the first surgery. Adjustments and modifications may be made after the first surgery, if indicated. In the event of specially identified circumstances, such as new procedures or species for the investigator or investigator's personnel, or surgical outcomes that are not well defined, the BRSF Manager and/or Attending Veterinarian will arrange to be present during the first surgery(s).

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.

To date, the operating rooms have only been used for rodent surgeries. The two operating rooms are positive pressure relative to adjacent support areas. Additionally, they can be accessed once you are in the surgical suites area which restricts traffic flow and non-essential personnel. Animals are brought from the general housing area to the animal preparation area, where they are given an initial surgical prep including clipping and vacuuming of hair, which limits the amount of dirt, hair and dander contaminating the surgical room. These rooms are restricted to appropriately attired staff. Only necessary personnel, attired with the

appropriate surgical clothing (scrubs, caps, masks, and shoe covers) are required to be worn in the operating areas during an aseptic procedure.
Surgical support areas consist of an animal preparation area, instrument and supply storage area also containing a surgeon's scrub/preparation area. The animal preparation area (Patient Prep room) is across the hall from the operating rooms. The instrument storage and supply areas along with the surgeon prep area is located in the OR Support Room that bridges the space between the operating rooms and have direct access to the main corridor of the surgical suites area. All areas have epoxy-coated walls and ceilings and troweled epoxy-coated floors. The surgeon preparation area has a foot pedal-operated stainless steel scrub sink. The OR Support room has a stainless steel counter with sink and cabinets for supply storage. The Patient Prep room has a stainless steel sinks and counter with cabinets for supply storage.
Animals recovering from surgery are monitored in the Recovery room before returning to general housing. This room has the same finishes as the others in this area.

Construction Features of Operating Rooms
a) Interior Surfaces
Ceilings and walls are composed of drywall sealed with epoxy paint. Floors are poured concrete finished with troweled epoxy.

b) Ventilation System
All room air is 100% fresh air. Operating Room air changes are 11-13 air exchanges/hour.

c) Lighting
Overhead panels with fluorescent lights provide room illumination while Steris Amsco Gemini ceiling mounted lights provide specific surgical lighting.

d) Outlets
All electrical outlets and circuits are connected to a Bender Line Isolation panel.

e) Scavenging
Each of the six surgical stations has a scavenging drop for waste anesthetic gases.

f) Fixed Equipment
The only fixed equipment in the operating rooms is the surgical lights suspended from the ceiling and wall-mounted radiographic viewers. The rooms are equipped with ceiling mounted hookups for oxygen, nitrous oxide, and suction.

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 Institutional Animal Care and Use Committee defines a major operative procedure, according to the description in the Guide, as one in which a body cavity is penetrated and exposed or one which produces substantial impairment of physical or physiologic function. Minor survival surgery does not expose a body cavity and causes little or no physical impairment.

b. How is non-survival surgery defined?

A non-survival procedure is defined as one in which the animal is euthanized after surgery has been performed and/or before regaining consciousness from anesthesia.

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

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

Aseptic procedures require: 1) clipping and surgical site aseptic scrubbing of the patient in a separate room from where the surgery will actually be performed, 2) preparation of the surgeon, which includes a separate scrub area for non-rodent survival surgeries, 3) sterile gloves for all survival surgeries, and a cap, mask, sterile gown and shoe covers, and 4) preparation of the operating room. The Institutional Animal Care and Use Committee must approve all surgical sites. Non-rodent survival surgeries are performed only in Operating Rooms One or Two. Personnel and procedures would be monitored by an assigned operating room technician for adherence to practices consistent with aseptic techniques.

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

Sterile clothing (gowns and gloves) can be obtained pre-packaged from commercial vendors. Equipment can be autoclaved in the facility's Castle steam sterilizers. Any liquid sterilants used would need to be approved for use by the IACUC on a case-by-case basis with due consideration for animal welfare and scientific outcomes based on a review of current relevant literature, and consistent with expected surgical outcomes.

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

Every effort is made so that instruments do not have to be re-sterilized between serial surgeries, such as having duplicate surgical packs of instruments sterilized and ready.
If instrument re-sterilization between serial rodent surgeries is necessary than any liquid sterilants used would need to be approved for use by the IACUC on a case-by-case basis with due consideration for animal welfare and scientific outcomes based on a review of current relevant literature, and consistent with expected surgical outcomes. Also, for re-sterilization between serial rodent surgeries and upon IACUC approval, a Hanson-Smith Germinator 500 dry bead sterilizer is available for use. This unit is effective when rapid decontamination of micro-dissecting instruments is needed. The unique stainless steel glass bead bath remains at a constant 500 degrees F, allowing one to insert the tips of instruments whenever you wish to decontaminate them.

d. Indicate how effectiveness of sterilization is monitored.

Sterility is monitored via the use of autoclave tape and a Sterilometer Steam Strip placed in the center of each instrument package. The surgical packs are taped closed using autoclave tape as another indicator to visually check that the autoclaves come up to the correct temperature and steam pressure. A Biological Spore Indicator test is run once a month to monitor how effectively the autoclaves kill bacteria. A sterilizer mechanical air removal test (S.M.A.R.T) pack is also run through the autoclaves once a month to evaluate the efficacy of air removal and steam penetration in the pre-vacuum sterilizers. The autoclaves are covered under a preventive maintenance program with a commercial vendor and are serviced four times a year to ensure they stay in good running condition and continue to operate properly.

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

In general, investigators and their designated, IACUC-approved personnel are responsible for conducting surgical procedures. Instruction in equipment usage and maintenance, and procedural training and oversight of personnel is provided by BRSF staff. On occasion, BRSF staff or the Attending Veterinarian may provide surgical support for specific procedures, if identified as warranted by the investigator, IACUC or Attending Veterinarian.

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.

Monitoring for all species is performed and documented on the animals' anesthetic health record by the surgical staff. Monitoring for survival and non-survival procedures is the same and includes routine evaluation of anesthetic depth and

physiologic functions and conditions, such as body temperature, cardiac, and respiratory rates and pattern. Fluid therapy and intraoperative analgesics may be given to help maintain normal body temperature and to minimize cardiovascular and respiratory disturbances caused by anesthetic agents.

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.

The licensed veterinary technicians and/or research personnel provide the post-operative care as described in the investigator protocol with approval from the Attending Veterinarian. Animals are placed in recovery cages in the surgical recovery room adjoining the operating suite immediately after surgery or may be taken directly back to general housing if they appear to be stable enough. A veterinary technician observes and monitors the animals until stable. Monitoring consists of maintaining appropriate body temperature, a circulating water heating blanket may be employed, vital signs such as heart rate, respiratory rate, and body temperature may be checked periodically, state of consciousness, and observation of the manifestation of pain. Animals are not left unattended until they achieve the ability to obtain sternal recumbency, their vital signs have normalized, and there is no evidence of the need for additional analgesia. If the veterinary technician has reason to suspect that an animal's condition may deteriorate overnight or knows that additional analgesia may be required, arrangements are made for someone to check on the animal as needed during the night. When an animal's condition normalizes and stabilizes it can then be returned to regular housing. In addition the animal may have an Anesthesia Monitoring Chart and a Post-operative Daily Treatment Chart maintained by the technicians and this becomes part of the animals' General Health Records and is kept with the animal at all times. The information recorded includes any physical, medical, laboratory, anesthetic, and surgical data results, and any treatments that may have been given.

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

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

Licensed veterinary technicians and/or research personnel monitor all patients post operatively or post procedure for signs of pain and distress and communicate concerns with the Attending Veterinarian. Investigators provide information on the animal usage application that addresses the category of pain or distress an animal may experience. This information is then used by the Attending Veterinarian, along with further consultation with the investigator if needed, to make an assessment as to the level of pain. This assessment remains a dynamic process as long as the project is active.

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

All personnel responsible for monitoring animal wellbeing, including species-specific behavioral manifestations as indicators of pain and distress, are required by the IACUC to complete CITI Program Training courses before carrying out these duties. The courses include, Working with Animals in Biomedical Research, and any species-specific courses for the species they are working with such as, Working with Mice in Research Settings, Working with Rats in Research Settings, etc. These courses cover such topics as Aseptic Surgery, Minimizing Pain and Distress, How to Recognize Pain and Distress in Animals, etc. In addition personnel receive one-on-one training from the PI and/or the Attending Veterinarian and the BRSF Manager in proper monitoring techniques and documentation thereof. The Attending Veterinarian, the BRSF staff and the PI oversee personnel until they prove themselves proficient to carry out this responsibility. For BRSF personnel this may include AALAS training for those individuals with AALAS certification.

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.

Mouse -	Ketamine
	Xylazine
	Isoflurane
	Alcaine Ophthalmic
	Buprenorphine
Rat -	Ketamine
	Xylazine
	Isoflurane
	Alcaine Ophthalmic
	Buprenorphine
Guinea Pig –	Ketamine
	Xylazine
	Buprenorphine
	Isoflurane

Additionally, non-pharmacologic procedures may include: separation of animals on which procedures are being performed; wrapping of animals for handling; and sequential handling of animals to desensitize to manipulation and procedures.

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

At the veterinary consultation, investigators propose anesthetic and analgesic agents, dosages, and routes of administration with their protocol submission to the Institutional Animal Care and Use Committee. These agents are generated from a list of common analgesic and anesthetic dosages, and routes of administration provided in Oakland University's Training and Information Manual for Animal Care and Use or from the investigator's own investigations, literature searches, and research. Required in the protocol application is documentation of independent research and literature searches for agents used. The Attending Veterinarian may also give the investigator suggestion for appropriate drugs and agents commonly used at the time of the veterinary consult. The Attending Veterinarian provides recommendations and advice based on approved and accepted methods as determined by appropriate literature, experience, and/or consultation with peers and other professional authorities.

Euthanasia agents and methods are determined based on recognized authoritative sources such as the American Veterinary Medical Association Panel on Euthanasia. If modifications or additions to the approved protocol arise after an experimental procedure is initiated, the Attending Veterinarian determines anesthetic and analgesic agents to be used based on the animal's condition and consultation with the investigator.

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.

All analgesic and anesthetic agents used on animals undergoing procedures are administered and monitored by licensed veterinary technicians, the investigators, or their research staff that are approved for and trained in the administration of such agents. The dosages, volume of drug given, and route of administration, are recorded on the animal's cage card and individual general health records. Responses or lack thereof to medications are also noted, and then reviewed by the Attending Veterinarian and adjusted as needed, in consultation with the investigator. Adjustments in husbandry may be made to diminish pain and distress, such as feeding methods (e.g. floor feeding), temperature adjustment, etc.

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.

A veterinary consultation is required in preparation of protocols requiring the use of neuromuscular blocking agents. The use of a neuromuscular blocking agent in an animal manipulation will require a justification with extensive detail on the instrumentation/procedures used for determining that adequate analgesia is maintained. All study records need to document that maintenance of adequate

levels of anesthesia and analgesia during the use of neuromuscular agents is monitored and maintained.

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

Prior to each use surgical staff checks the anesthetic machine and equipment for leaks and functionality. Anesthetic agent and oxygen levels are checked for adequacy. When in use, the anesthetic machines are given routine maintenance once a month to ensure that all aspects of the machine are functioning and in good working order. Hoses, re-breathing bags, etc. are replaced as needed. When the machines are in service, the anesthetic vaporizers are sent out for service on an as needed basis and the vaporizers are calibrated as per manufacturers recommendations.

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.

Mice - CO_2 asphyxiation, cervical dislocation with pre-sedation or anesthesia (unless scientifically justified to be withheld), the method of assurance is bilateral pneumothorax
Rats - CO_2 asphyxiation, cervical dislocation, decapitation with pre-sedation or anesthesia (unless scientifically justified to be withheld), the method of assurance is bilateral pneumothorax
Guinea Pigs - CO_2 asphyxiation, the method of assurance is bilateral pneumothorax
Frogs - Overdose of Tricaine methanesulfonate (MS-222) a 10% solution (5mg/ml) for an immersion time of 20 to 30 minutes. Method of assurance consists of decapitation.
Tadpoles – Overdose of Tricaine methanesulfonate (MS-222) a 10% solution (5mg/ml) for an immersion time of 20 to 30 minutes. Method of assurance consists of pithing or placing in a centrifuge tube and freezing in a -70 ° C freezer.

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

Euthanasia is performed by trained and licensed veterinary technicians, BRSF trained staff, or by the principal investigators and members of their research staff,

who have demonstrated via training and experience, their competence in the proper euthanasia technique. If investigators or their staff is performing euthanasia, it is always under the approval of the IACUC and direction of the Attending Veterinarian. The EZ Euthanex CO_2 System used in the facility is fully automated and designed to assure standardized compliance with the AVMA panel on euthanasia guidelines. The system shuts down if preset parameters are not functioning. A warning light indicates loss of CO_2 supply. Staff changes the CO_2 supply tank as needed. The machine is serviced by the manufacturer if needed.

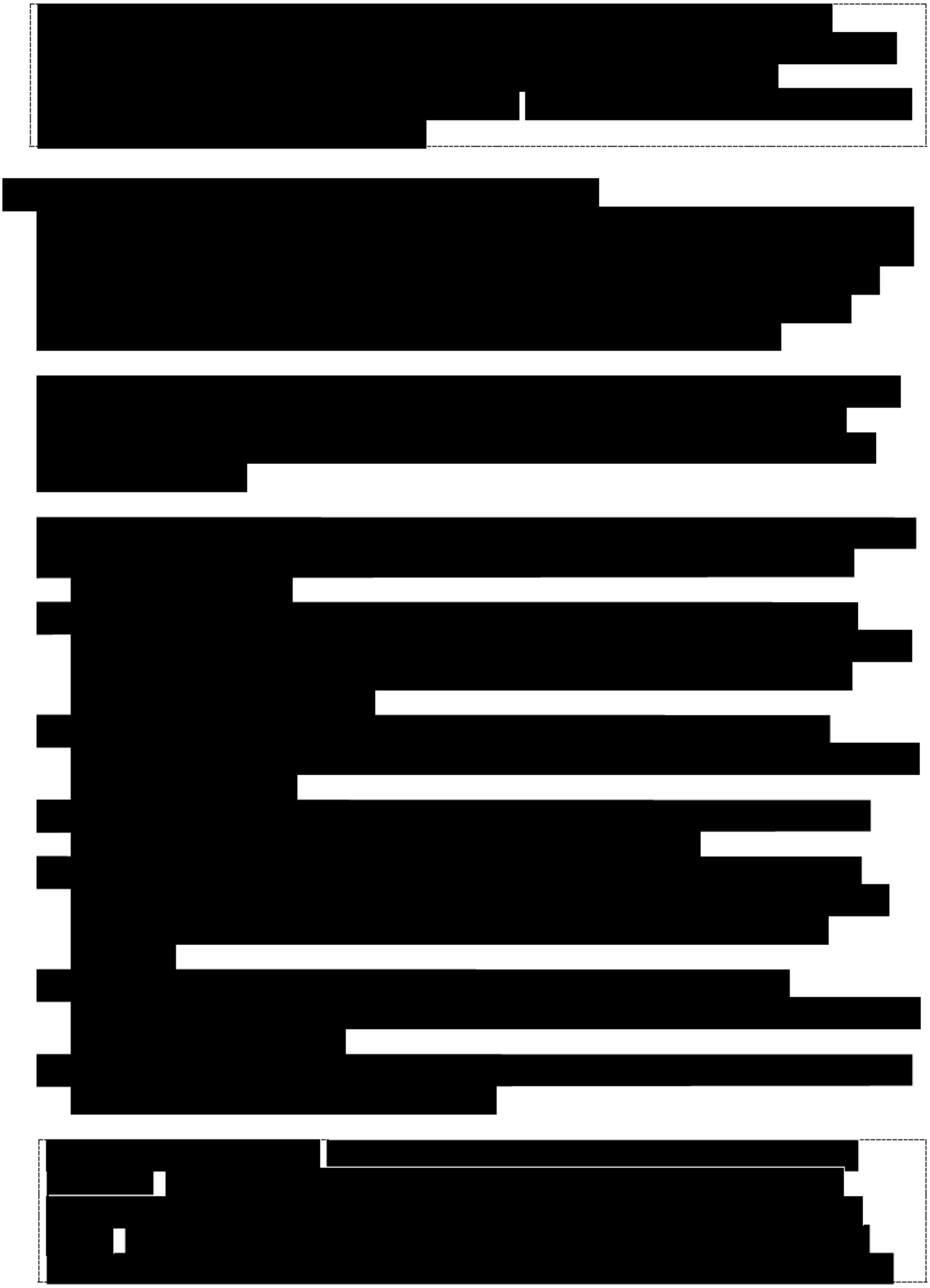
3. Describe the methods used to confirm death of an animal.

Euthanized animals are observed for cessation of respiration and heart rate. Severance of the aorta, removal of essential organs (i.e., heart) or bilateral pneumothorax is performed on rodents. Additionally, bilateral pneumothorax is performed on guinea pigs to assure death. Frogs and amphibians are decapitated and tadpoles are either pithed or place in a centrifuge tube and frozen in a -70º freezer.

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.



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.

The criteria used to define a Satellite Animal Housing Area:
A satellite facility of Oakland University, for the purpose of this Program Description, is defined as an animal use area, such as a researcher's lab, that is located outside of the core or centrally managed area (BRSF) in which animals are housed for more than 24 hours, and/or areas where any form of surgical manipulations (minor, major, survival, non-survival) are performed. These include animal use areas where USDA covered species or animals owned by Oakland University are housed in facilities that Oakland University owns and operates.

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 IACUC requires principal investigators provide justification in the animal protocol for housing animals outside of the centrally-maintained (BRSF) facility. They must also include a description of husbandry procedures, who will be responsible for providing food, water, and daily animal checks, water quality testing, emergency and disaster preparedness, and security. These areas come under the same regulatory oversight as the centrally-maintained facility and are included in the semiannual inspections and program reviews as well as post-approval monitoring. The Attending Veterinarian has access to all animal use areas.

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.

[redacted]

[redacted]

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

There have been no animal losses or health problems resulting from power, HVAC, or other life support system failures. If such incidents had occurred than the reporting of such incidences would have followed the procedures outlined in the IACUC's standard operating procedure (SOP) entitled, Guidance on Prompt Reporting of Unanticipated Problems and Unexpected Deaths of Research Animals. Such incidences would be immediately reported to the Attending Veterinarian, the IACUC, the IO, and the Principal Investigator by the BRSF Manager or staff. If deemed appropriate the corresponding regulatory body would also be notified.

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

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

[redacted]

[redacted]

2. Other Animal Program Support Facilities

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

There are no other Animal Program Support Facilities

Appendix 1: Glossary of Abbreviations and Acronyms

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

Abbreviation/Acronym	Definition
IO	Institutional Official
AV	Attending Veterinarian
BRSF	Biomedical Research Support Facility
OU	Oakland University
IACUC	Institutional Animal Care and Use Committee
OLAW	Office of Laboratory Animal Welfare
PHS	Public Health Service
USDA	United States Department of Agriculture
AVPR	Associate Vice President for Research
EH&S	Environmental Health and Safety
ISCRM	Institute for Stem Cell and Regenerative Medicine
URC	University Research Committee
CBR	Center for Biomedical Research
NIH	National Institutes of Health
NSF	National Science Foundation
NEI	National Eye Institute
AHA	American Heart Association
ROPARD	Retinopathy of Prematurity and Related Diseases
NRC	National Research Council
IRB	Institutional Review Board
IBC	Institutional Biosafety Committee
RLATG	Registered Laboratory Animal Technologist
DACLAM	Diplomate of the American College of Laboratory Animal Medicine
ORA	Office of Research Administration
MOU	Memorandum of Understanding
CITI	Collaborative Institutional Training Initiative
SDS	Safety Data Sheets
MALAM	Michigan Academy of Laboratory Animal Medicine
LATG	Laboratory Animal Technologist

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
AALAS	American Association for Laboratory Animal Science
CEU	Continuing Education Credits
MAVT	Michigan Association of Veterinary Technicians
MISMR	Michigan Society for Medical Research
LAT	Laboratory Animal Technician
LVT	Licensed Veterinary Technician
LMT	Licensed Massage Therapist
AUVA	Application for Use of Vertebrate Animals
RSC	Radiation Safety Committee
OHSP	Occupational Health and Safety Program
PI	Principal Investigator
GHC	Graham Health Center
CFR	Code of Federal Regulations
LAA	Laboratory Animal Allergens
PPE	Personal Protective Equipment
chp	Changes per hour
MIOSHA	Michigan Occupational Safety and Health Act (State level)
OSHA	Occupational Safety and Health Act (National level)
OR	Operating Room
SOP	Standard Operating Procedure
ENU	N-ethyl N-methyl nitrosourea
BSL2	Biosafety Level 2
LPS	Lipopolysaccharide
STZ	Streptozoticin
RAM	Research Application Manager
COI	Conflict of Interest
FCR	Full Committee Review
DMR	Designated Member Review
CRT	Critical Response Team
CC	Command Center
CHP	Central Heat Plant
MSC	Mathematics and Science Center
DEA	Drug Enforcement Agency

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
DH	Dodge Hall
EPA	Environmental Protection Agency
NSG	NOD scid gamma mice
PIN	Personal Identification Number
LP	Local Processor
RSF	Reportable Square Feet
GFI	Ground-fault Circuit Interrupter
PRRL	Pediatric Retinal Research Lab
ENT	Ear Nose and Throat

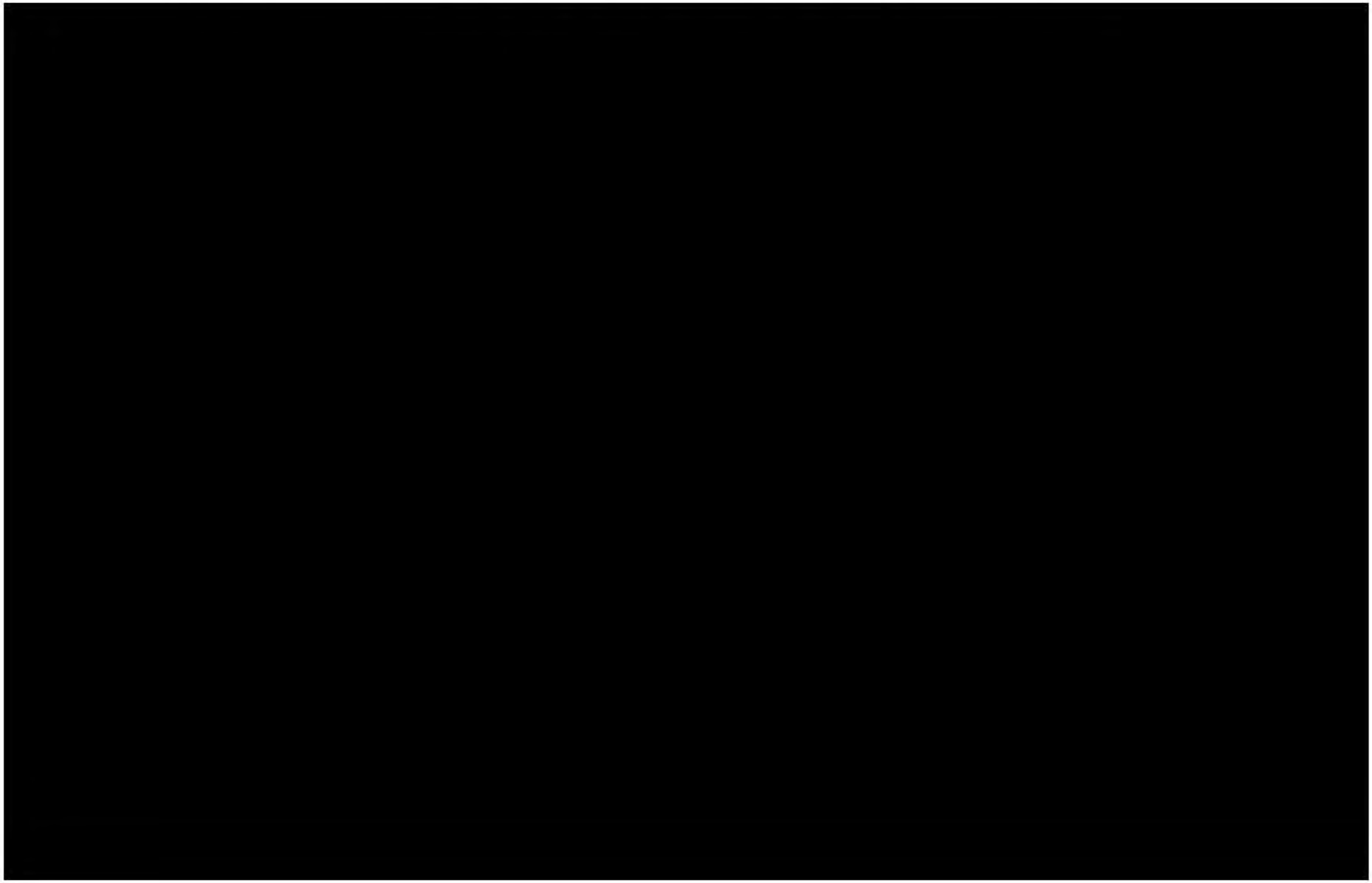
Appendix 2: Summary of Animal Housing and Support Sites

[redacted]

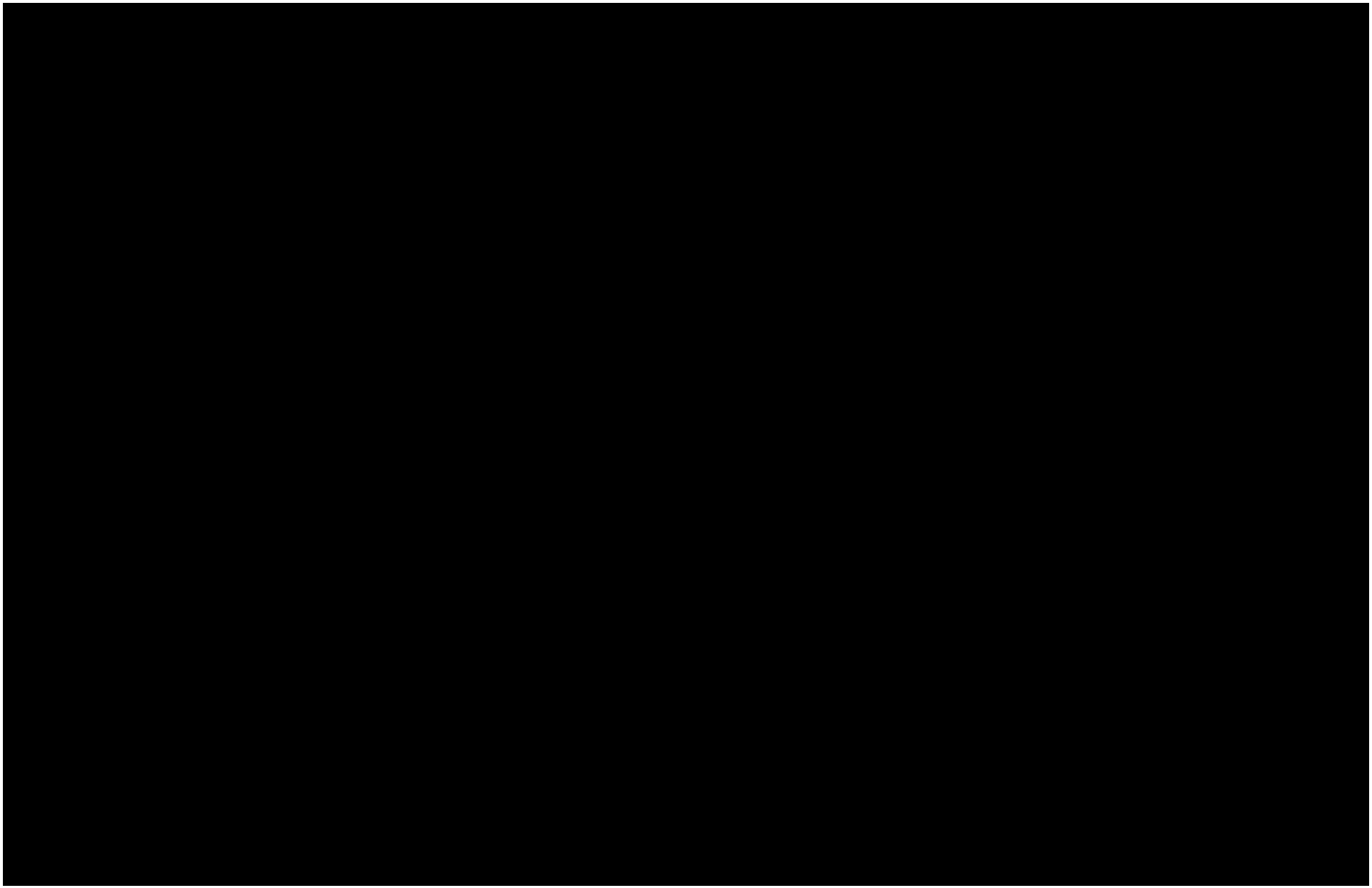
[b]Campus or site map(s) may also be provided in lieu of this information

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.

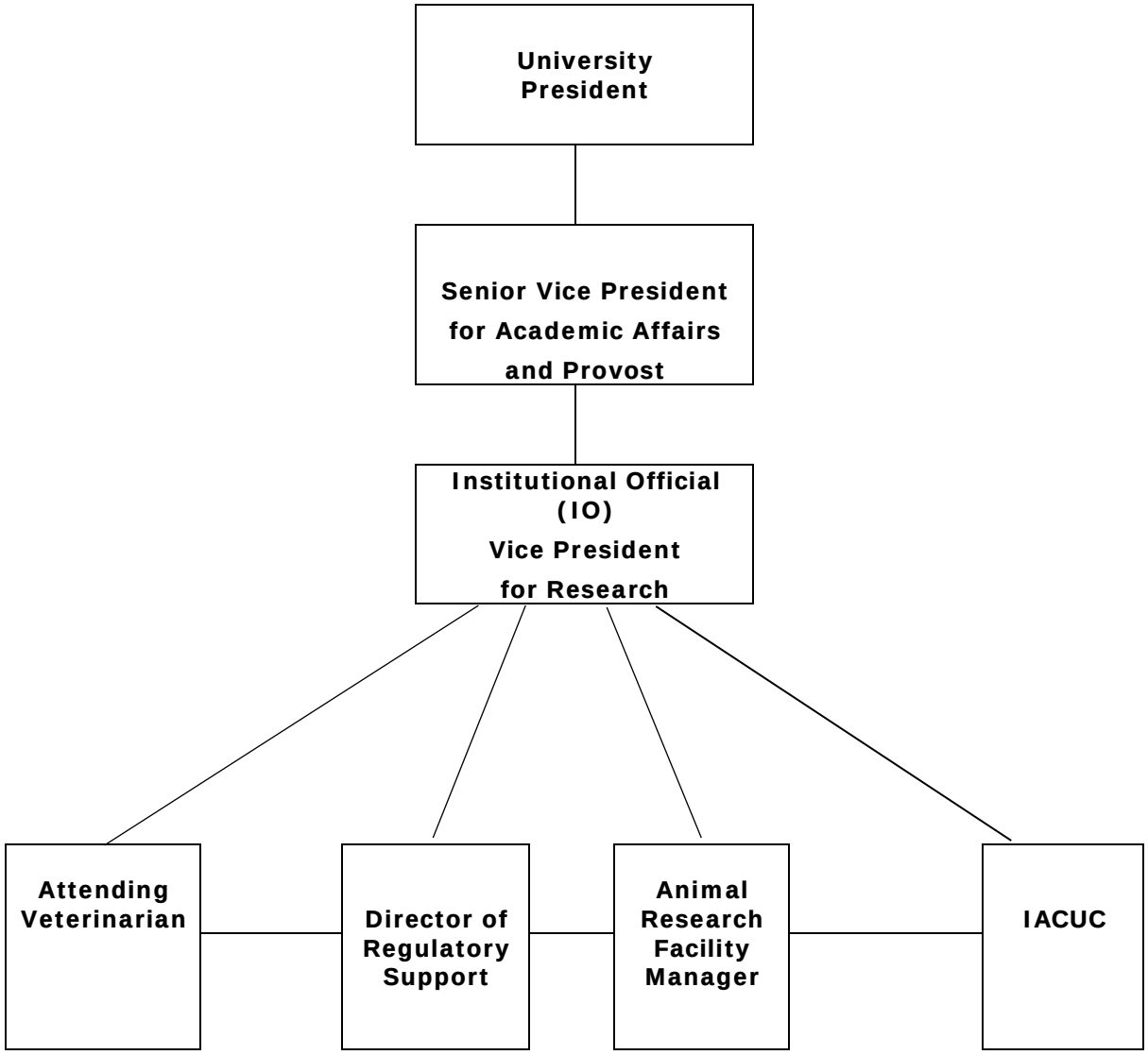


Appendix 3: Line Drawings



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 5: Animal Usage

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

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Gender Differences in Diabetes in Serotonin Receptor Expression and Function	15061-R2	[redacted]	Rat	336	D	√				√	
Population Dynamics of the Wood Frog *Rana Sylvatica*	16011		Frog	~12,000	D						√
The Influence of Leaf Litter Composition on Predator-Prey Interactions in Aquatic Habitats	16022		Tadpoles	4,500 1,500	C E						√
Retinal Regeneration in a Mouse Model Using Stem Cells	15094		Mouse	72	D					√	
Derivation of Mouse Embryonic Fibroblasts as Feeder Layer for Growth of Embryonic Stem Cells	16041		Mouse	30	C						
Retinal Regeneration in a Model of NMDA-Induced Retinal Cell Degeneration Using Stem Cells	16061		Mouse	72	D					√	
Assessment of Pluripotency of Embryonic Stem Cells by Teratoma Assay	17031		Mouse	36	D					√	
Intervertebral Disc Regeneration Using Stem Cell Therapy	17051		Rat	84	D					√	
Treatment of Memory Impairments Associated to Fetal Alcohol Exposure and Dysfunctions in the Integrin Linked Kinase (ILK) Pathway Using a Tyrosin Kinase b (Trkb) Receptor Agonist	16013-R2		Rat	272	C			√		√	
Strategies to Address Relapse and Post-relapse Attenuation of Fear	16014		Rat	2,160	C			√			

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Behavioral Assessment of Glutamate Receptor Expression on Memory Reconsolidation	17061	[redacted]	Rat	720	C			√			
Exposure of Mouse Lenses to UVB Light in Vivo	16063		Mouse	78	D						
Hyperbaric Oxygen Treatment of Guinea Pigs	16121		Guinea Pig	196	C						
Xenopus laevis System for Investigation of Vertebrate Photoreceptor Structure and Trafficking	16051		Frog	~3,506	C					√	
Investigation of the Molecular Basis of Rod and Cone Photoreceptor Structure	16052		Mouse	327	D					√	
Mechanisms Underlying Rod and Cone Photoreceptor Outer Segment Integrity	17053		Mouse	682 628	C D					√	
Investigations on Cell-Cell Interactions During Wound Repair in the Corneal Endothelium	16021		Rat	280	C						
Human Cancer Cells Xenograft in Immunocompromised Nude Mice J:NU	15064		Mouse	120	D					√	
Study the Function of SLC39A8 (ZIP8) in Transgenic Mice	15065-R2		Mouse	778	D					√	
Functional Study of ZIP8 in ZIP8 Liver-specific Knockout Mouse	17073	[redacted]	Mouse	4 48	B D						
Improved STZ-Diabetic Rat Model	14121		Rat	480	D					√	
VEGF's Longitudinal Effect on the Retina and Retinal Vasculature in Vivo	15091		Rat	390	D						
Intraocular Drug Testing - Norrin Drug Development	16112		Rat	375	D					√	
Rodent Colony Health Surveillance	15022		Mouse Rat	342 90	B B						
BRSF Animal Holding Protocol	16113		Varied	Varied	B						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
A Metabolic Theory Approach to the Thermal Biology of Parasitism	15101-R1	[redacted]	Amphibian	2,391 1,224	C E					√	√
The Study of Gut Immunity	16062-R2		Mouse	2,550 450	B D						
The Study of Gastrointestinal Pathobiology	16122		Mouse	286 186	B E						
Undergraduate Laboratories for Biology 301:Ecology	15092		Fish	1800	C						√
Impacts of Invasive New Zealand Mud Snails on the Diets and Condition of Michigan Fishes	16111		Fish	630	C						√
Cognitive Bias in Rescued Domestic Animals	15062		Equine	120	C						√
Gorilla Aesthetics, Emotions and Choice II	15071		Gorilla	3	B						√
Enrichment and Cognitive Testing in Bears II	15072		Bears	8	C						√
Reputation Formation in Domestic Cats (*Felis silvestris catus*)	16043		Cats	60	B						√
Catch as Cats Can: Cooperation in Domestic Cats	17052		Cats	80	C						√
Sequence Learning in Domestic Cats (*Felis silvestris catus*)	17101		Cats	40	B						√
The Identification and Characterization of Thrombosis and	17071		Mouse	10,520 990	D E					√	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Atherothrombosis Modifier Genes											
Binge-drinking on Sweetened Fluid: Later Effects on Ethanol Self-administration and Sensitivity to Pharmacological Treatment.	16064-R1	[redacted]	Rat	192	C			√			
Functional Organization of the Retinal Dopaminergic Network	15081-R1	[redacted]	Mouse	22 1,888	B D						
Retrograde Signal Transmission in the Mouse Retina	17072	[redacted]	Mouse	78 800	B D						

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

Pain/Distress Classification Description/Definition, if applicable:

Appendix 5: Animal Usage

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

Animal Type or Species	Approximate Annual Use
Guinea Pig	36
Rat	140
Mouse	2,481
Fish	37
Amphibians	4,756

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

Appendix 6: Personnel Medical Evaluation Form

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

Oakland University

Route Campus Mail
Attention: Nancy Jensen
Department: GHC Clinic

Annual Health Review for Animal Handlers

Oakland University employees having laboratory animal exposure associated with their employment, study, or work on an approved Institutional Animal Care and Use Committee (IACUC) protocol at this institution are required to undergo a health review upon employment and at yearly intervals. A health review is recommended for all other research personnel whose activities place them at reasonable risk of injury or illness, and who are involved in the direct care of vertebrate animals and their living quarters, and those individuals who have direct contact with animals (live or dead), their viable tissues, body fluids or wastes. Please complete this form and mail to Graham Health Center (2200 N Squirrel Rd, Rochester Hills, MI 48309). Do not give this form to your supervisor. Please call the Biomedical Research Support Facility (BRSF) at ext. 4440 & 4441, or Laboratory Safety & Compliance at 4314 if you have any questions.

First Name:	Last Name:	G#:
Home Phone:	Work Phone:	Email:
Dept/Address:	Job Title:	Student: ☐Yes ☐No
Home Address:		
PI or Supervisor Name:	Supervisor Phone:	

Animal Work Status

Check the below box which accurately describes your current animal work status:

- ☐I am currently working with any of the following: lab animals, animal tissues, cages, animal waste or bedding. ***(If Checked - Proceed to page 2 "Health History" portion of form.)***
- ☐I am listed on an active animal protocol and may eventually work with lab animals or materials which have come in contact with lab animals. ***(If Checked - Proceed to page 2 "Health History" portion of form.)***
- ☐I am listed on an active animal protocol, but will not conduct any work in animal areas or with materials which come in contact with animals. **(If this box is checked, no further information is required. Stop completing the form and route form as instructed in top right corner of form.)**
- ☐I am no longer working with lab animals or materials which come in contact with lab animals. **(If this box is checked, no further information is required. Stop completing the form and route form as instructed in top right corner of form.)**

1 of 4 Revised: 6/20/2013

Health History

1. In the past year have you developed any of the following::
   - Asthma? ☐Yes ☐No
   - Skin rashes, especially after glove use? ☐Yes ☐No
   - Allergy testing, injections or medications? ☐Yes ☐No
   - Chronic bronchitis, emphysema or COPD? ☐Yes ☐No
2. Immune system suppression? (Cancer, chemotherapy, radiation therapy, chronic diseases, HIV, organ transplant, spleen removal.) ☐Yes ☐No
3. If yes to any of the questions above, please explain:

4. Have you ever been fit tested for a respirator in the past 12 months? ☐Yes ☐No
   If "Yes", provide date tested:_____
5. Do you smoke tobacco? ☐Yes ☐No
6. Do you take any medications on a daily basis (including over the counter)? ☐Yes ☐No
   If yes, please explain:

Allergy History – Past 12 months

In the past 12 months have you developed allergies to any of the following? (Check all that apply. Specify allergen for each item checked.)

☐Grasses:_____ ☐ Chemicals:_____
☐Medications:_____ ☐ Latex:_____
☐ Trees:_____ ☐ Wood :_____
☐ Food products:_____ ☐ Perfumes:_____
☐ Tobacco smoke:_____ ☐ Other:_____
☐Animals (specify):_____

2 of 4 Revised: 6/20/2013

Allergy History – Past 12 months (continued)

In the past 12 months:

Have you received emergency medical treatment due to an allergic reaction? ☐Yes ☐No

Did you require medicine for an animal allergy? ☐Yes ☐No

If you developed allergies to animals in the past 12 months please check all symptoms that develop when exposed to specific animals.

- ☐ Skin rash or itchiness
- ☐ Sneezing
- ☐ Nasal congestion / drainage
- ☐ Shortness of breath/cough
- ☐ Nose/ Throat Irritation
- ☐ Wheezing/chest tightness
- ☐ Facial or tongue swelling
- ☐ Itching, tearing of eye

Other – List:

Do you have allergic symptoms when you are NOT around animals? ☐Yes ☐No

Estimate the hours per day you handle animals:

☐ 0 hours ☐ 1 hour ☐ 2-4 hours ☐ more than 4 hours

Estimate the hours per day you work in the animal cage areas:

☐ 0 hours ☐ 1 hour ☐ 2-4 hours ☐ more than 4 hours

Indicate the task you perform while working in the animal cage areas:

What Species of Animal(s) Do You Currently Work With?

Check all boxes that apply.

- ☐ Non-human Primates
- ☐ Pigs - swine
- ☐ Cows, Calves
- ☐ Sheep
- ☐ Horses
- ☐ Amphibians (Turtles, Frogs)
- ☐ Hamster
- ☐ Chickens
- ☐ Gerbils
- ☐ Guinea Pigs
- ☐ Goats
- ☐ Dogs
- ☐ Cats
- ☐ Rats
- ☐ Mice
- ☐ Birds
- ☐ Reptiles (snakes, lizards)
- ☐ Chicken embryo
- ☐ Wild Rodents
- ☐ Fish
- ☐ Rabbits

Other Mammals Currently Working With- Please List:

Do you use environmental controls and personal protective equipment while working? ☐Yes ☐No

Specify: ☐Gloves ☐Surgical Mask ☐N95 Respirator ☐Other:

I understand that working with live animals may lead to the development of allergies and/or severe asthma. I certify that the above information is complete and correct to the best of my knowledge and belief. I authorize the GHC to contact my supervisor and release necessary information to control exposures in the work environment if needed, based on the results of this health screening. I understand that intentional misstatements or omissions may be grounds for disciplinary action which could include termination. I understand that a health evaluation may be required.

Name Signature Date

For GHC use only:

- ☐form reviewed, animal handler cleared and department notified
- ☐recommend health evaluation, supervisor notified
- ☐need additional information from employee/student

Provider Signature Date

Patient Name G#

Appendix 6: Personnel Medical Evaluation Form

Route Campus Mail:
Attention: Nancy Jansen
Department: GHC Clinic

Oakland University
Occupational Health Program for Animal Handlers
Declination Statement

Oakland University's **Occupational Health Program for Animal Handlers** is a medical surveillance program designed to evaluate, control, and monitor Animal Handler (employee, student, research personnel, or volunteer) exposures where laboratory animals are in use. The following statement of declination must be signed by an individual that has access to laboratory animal use areas, but chooses not to participate in the university's medical surveillance program. This statement can only be signed after completion of **Research Hazards Awareness Training**, which includes information on potential research hazards when working with or around laboratory animals including information on allergies, their signs and symptoms, associated health risks, and benefits of enrollment in the university's **Occupational Health Program for Animal Handlers**. This declination statement is not a waiver; participation in this medical surveillance program can be initiated at a later date if laboratory animal exposures are still possible.

Declination Statement:
I understand that because I may come into contact with animals during the course of my work, research, or course work, I may be at risk of developing allergies to animals. I have completed **Research Hazards Awareness** training and have been offered the chance to participate in Oakland University's **Occupational Health Program for Animal Handlers**. I understand that allergies can range from very mild (such as watery itchy eyes) to life-threatening (swelling and tightening of the throat, and trouble breathing) symptoms.

I choose not to participate in the medical surveillance program at this time. I understand that by not participating in the program, potentially serious symptoms may not be able to be identified as allergy symptoms early in their course. Therefore, preventive treatments could be delayed, though treatment of symptoms as they arise still could be done. This could result in potentially serious long-term health problems. If, in the future, I continue to come in contact with laboratory animals and want to participate in Oakland University's medical surveillance program, I can enroll by submitting a current **Health Review for Animal Handlers** medical surveillance questionnaire. I understand that if I choose in the future to submit a completed questionnaire, I must complete a new questionnaire every year while I am a part of the medical surveillance program.

Name:	Date of Birth:
Signature:	Date Signed:
Grizzly ID:	Department:
University Affiliation: ☐Student ☐Employee ☐Volunteer ☐Other (Explain):	

Appendix 7: IACUC/OB Membership Roster

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

IACUC Roster			
Name of Member	**Degree/Credentials**	**Position Title/Occupational Background**	**PHS Policy Membership Requirements**
Amy Banes-Berceli	**Ph.D.**	**Associate Professor Biological Sciences**	**Scientist Member Vice Chair**
Claudio Cortes	**Ph.D., D.V.M.**	**Assistant Professor Department of Biomedical Sciences**	**Scientist Member**
James Nugent	**Ph.D.**	**Associate Professor Department of Writing and Rhetoric**	**Nonscientist Member**
J. Dean Masters	**B.A.**	**Library Assistant III**	**Nonscientist Member**
Louis Miller	**M.S.**	**Retired Public School Teacher**	**Nonaffiliated Member**
Lori Penman	**D.V.M.**	**Attending Veterinarian**	**Veterinarian Member**
Janet Schofding	**B.S., RLATg, LVT**	**BRSF Manager**	**Member**
Keith Williams	**Ph.D.**	**Associate Professor Department of Psychology**	**Chair**
Dao Qi Zhang	**Ph.D.**	**Assistant Professor Eye Research Institute**	**Scientist Member**

Appendix 8: IACUC/OB Minutes

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

OAKLAND UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MINUTES
Biomedical Research Support Facility

August 22, 2017

Members Present: Amy Banes-Berceli, Lori Penman, Thomas Raffel, Janet Schofding, Keith Williams

Members Absent: Louis Miller, James Nugent, Dao-Qi Zhang

Others Present: Claudio Cortes*, Rebecca Sandborg

The meeting was called to order at 9:08 a.m.

Dr. Rebecca Sandborg introduced new IACUC member Dr. Claudio Cortes to the committee. He is from the Oakland University William Beaumont School of Medicine. Dr. Cortes gave a brief synopsis of his background. His appointment begins September 1, 2017, but attended today to meet the committee members and to observe how the meetings are conducted. He will be replacing Dr. Thomas Raffel on the committee. Dr. Raffel is stepping down from the committee in order to devote more time to his service commitments.

*Dr. Cortes left the meeting at 9:30 am.

Consent Agenda

The committee approved the following consent agenda:

1. Status of Protocols Given "Requires Modification" at a Previous Meeting
   - [redacted]
2. Status of Protocols Requesting Revision at Previous Meeting

- [redacted]

3. Protocols Given Administrative Approval since the Last Meeting
   - There were none

4. Protocols with Amendment Forms Approved for the Addition of Personnel since the Last Meeting
   - [redacted]

Continuing Business

1. [redacted]

   Upon IACUC request, the required modifications came back to the full committee for review.
   The committee reviewed the required modifications and determined that further modifications are necessary in order to secure full approval. The required modifications will be listed in the Committee Action Record and sent to the principal investigator. The IACUC chair appointed himself and Dr. Amy Banes-Berceli to be the designated member reviewers of the required modifications. This application received IACUC reference number 17071-RM2.

   The vote was: Yes-5; No-0; Abstained-0

New Business

1. Review of July 18, 2017 Meeting Minutes
   The minutes were approved with one minor change

   The vote count was: Yes-5; No-0; Abstained-0

   At this point in the meeting Dr. James Nugent joined the meeting via telecommunication (telephone via speaker phone) as per the criteria listed in OLAW's Notice Number NOT-OD-06-052 *Guidance on Use of Telecommunications for IACUC Meetings* when a convened meeting of a quorum of the IACUC is required under the PHS Policy on Humane Care and Use of Laboratory Animals

2. [redacted]

   The committee reviewed the request for revision and determined that the revisions required modifications in order to secure full approval. The required modifications will be listed in the Committee Action Record

and sent to the principal investigator. The IACUC chair appointed himself and Dr. Amy Banes-Berceli to be the designated member reviewers of the required modifications. This application received IACUC reference number 15101-R1-RM.

The vote count was: Yes-5; No-0; Abstained-0; Recused-1*

*Dr. Thomas Raffel recused himself and stepped out of the room during voting as this is his protocol.

Dr. James Nugent ended the phone call after voting

3. Review of the Annual Review Forms
The committee reviewed and approved the Annual Review Forms for the following IACUC-approved protocols:
    - Dr. Jennifer Vonk 15072
    - Dr. Sang Rhee 16062-R2

The vote count was: Yes-5; No-0; Abstained-0

Dr. James Nugent was called again to rejoin the meeting via the telephone conference call in order to have a quorum present for voting on Dr. Keith Williams' annual review form.

- Dr. Keith Williams 16064-R1

The vote count was: Yes-5; No-0; Abstained-1*

* Dr. Keith Williams abstained from voting as this is his annual review form

4. Review of Project Completion Summary Forms
The committee reviewed the Project Completion Summary Forms for the following IACUC-approved protocols:
    - Dr. Jennifer Vonk 14082-R1
    - Dr. Jennifer Vonk15093
    - Dr. Zijuan Liu 14111

5. Scheduling of the Next IACUC Meeting
The next IACUC meeting is scheduled for **Tuesday, September 19, 2017 at 9:00 a.m.** The Semiannual Program Review is scheduled for 8:00 a.m. the same day.

The meeting adjourned at 10:15 p.m.

Respectfully submitted,
Barbara A. Kooiman
Recording Secretary

NOTE – The IACUC did not meet in September 2017

Appendix 8: IACUC/OB Minutes

OAKLAND UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE MINUTES
Biomedical Research Support Facility

October 19, 2017

Members Present: Amy Banes-Berceli, Claudio Cortes, Louis Miller, Janet Schofding, Keith Williams. Dao-Qi Zhang

Members Absent: James Nugent, Lori Penman

Others Present: Domenic Luongo, Rebecca Sandborg

The meeting was called to order at 9:07 a.m.

Consent Agenda

The committee approved the following consent agenda:

5. Status of Protocols Given "Requires Modification" at a Previous Meeting
   - [redacted]

   [redacted]

6. Status of Protocols Requesting Revision at Previous Meeting
   - [redacted]

     The Principal Investigator has made the required modifications to the requested revisions of the application. The required modifications received Designated Member Review approval. The new IACUC reference number is 15101-R1.

7. Protocols Given Administrative Approval since the Last Meeting
   - There were none

8. Protocols with Amendment Forms Approved for the Addition of Personnel since the Last Meeting

- [redacted]

New Business

6. Review of August 22, 2017 Meeting Minutes
   There was a quorum present for the meeting to conduct business. However, there was not a majority of members present to approve the minutes because Dr. Claudio Cortes and Mr. Louis Miller had to abstain from voting due to their not having attended the August 22nd meeting. As a result, the committee did not have a quorum present and so voting on the minutes was tabled until the next meeting

7. [redacted])

   The committee reviewed this application and voted that the protocol requires modifications to secure full approval. The required modifications will be listed in the Committee Action Record and sent to the principal investigator. The IACUC chair appointed Dr. Amy Banes-Berceli and Dr. Claudio Cortes to be the designated member reviewers of the required modifications. This application received IACUC reference number 17101-RM.

   The vote count was: Yes-6; No-0; Abstained-0

8. Discussion on policies for special procedures (Guide, p 27-32) under Item 5 of the OLAW Semiannual Checklist was deferred until the next meeting.

9. Review of the Semiannual Report of the Inspection of Facilities and Program Review to the IO
   The report was passed around to the committee members to review and sign.

10. Review of the Annual Review Forms
    The committee reviewed and approved the Annual Review Form for the following IACUC-approved protocol:
    - Dr. Dao-Qi Zhang 15081-R1

    The vote count was: Yes-5; No-0; Abstained-0, Recused-1*

    *Dr. Zhang recused himself and stepped out of the room during the discussion and voting as this is his protocol.

11. Review of Project Completion Summary Forms
    The committee reviewed the Project Completion Summary Form for the following IACUC-approved protocol:
    - Dr. Dao-Qi Zhang 14081-R1

12. Scheduling of the Next IACUC Meeting
    The next IACUC meeting is scheduled for **Thursday, November 30, 2017 at 9:00 a.m.** The following meeting is scheduled for Tuesday, December 19, 2017 at 9:00 a.m.

13. Other Business
    Dr. Fay Hansen, who runs the organic farm, inquired as to whether or not she needs to get IACUC approval for raising live chickens as part of the teaching program of organic farm techniques. The IACUC determined that an IACUC application will need to be submitted for this matter. Dr. Banes-Berceli, who has been communicating with Dr. Hansen, will inform her that she needs to submit an IACUC application.

The meeting adjourned at 9:55 p.m.

Respectfully submitted,
Barbara A. Kooiman
Recording Secretary

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.

OAKLAND UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

APPLICATION FOR USE OF VERTEBRATE ANIMALS IN RESEARCH, TEACHING OR TESTING

PLEASE COMPLETE THIS APPLICATION FORM, SAVE IT TO YOUR SYSTEM, AND THEN UPLOAD IT TO YOUR ONLINE IACUC APPLICATION IN RAM 3.0

NOTE: The Use of Any Vertebrate Animals in Research, Teaching, or Testing without Prior Approval of the Institutional Animal Care and Use Committee (IACUC) is a Violation of Oakland University Policies and Procedures.

PART I To Be Completed Once Per Application

1. TITLE OF PROJECT:

2. BEGINNING AND ENDING DATES *(maximum – 3 yrs)*:

3. RESPONSIBLE PARTY INFORMATION:

Principal Investigator:	Title:	Office Phone:
Department:	Address:	
Responsible Faculty Member: (If PI is not a Faculty Member)	Title:	Office Phone:

Complete A. and B. below:

A. PI Emergency Contact Phone Number:
B. Person to contact in case of an emergency (other than the PI):

Phone Number:

Appendix 9: IACUC/OB Protocol Form

4. FUNDING SOURCE

Name: Grant # Submission Deadline:
Name of Anticipated Funding Source: Submission Deadline:
University Funding: Account #: Name:
Other Source: Name: Address:

NOTE: NIH requires written approval on all projects. This includes new grant applications, competitive renewals and renewals. All applicants will receive written notification of the results of the IACUC review.

5. PERSONNEL

Reminder: The "Final Rule" regarding financial conflicts of interest in PHS-funded research went into effect 8/24/2012. The Final Rule requires all investigators engaged in or planning to engage in PHS-funded research to disclose ***all personal significant financial interests (SFI)*** related to the Investigator's institutional responsibilities. This requirement also includes the financial interests of each investigator's spouse and/or dependent children.

If your study is PHS funded and includes any personnel on the project that meets the PHS definition of "investigator," you must contact the Office of Research Administration to submit a Significant Financial Disclosure Form. ***Investigators*** are defined as all individuals who are responsible for the design, conduct or reporting of the PHS-funded work. See OU's research policy and operational guidance on compliance with the FCOI Final Rule at http://wwwp.oakland.edu/research/compliance/

Use the following categories for function: 1-Euthanasia; 2-Anesthesia; 3-Surgery, 4-Postoperative care, 5-Nonsurgical Procedures, 6-Handling or Restraint of Animals, 7-Other (Explain).

Name:	Title:	Function:	Email Address:
Name:	Title:	Function:	Email Address:
Name:	Title:	Function:	Email Address:
Name:	Title:	Function:	Email Address:
Name:	Title:	Function:	Email Address:

Appendix 9: IACUC/OB Protocol Form

NOTE: Federal regulations require that all personnel involved in animal care and use be adequately trained to perform their duties, and it is the responsibility of the Principle Investigator to insure that this training takes place. Oakland University's training program for personnel consists of three parts:

(1) Specific training provided by the principal investigator and/or the staff of the Biomedical Research Support Facility (BRSF).

(2) Completion of IACUC required Collaborative Institutional Training Initiative (CITI) Program Training courses. **None of the personnel listed below may begin work until completion of the required CITI courses has been verified by the IACUC CITI Program Training Administrator**

(3) Completion of the Office of Environmental Health and Safety's (EH & S) **Research Hazards Awareness Training.** Schedule training by contacting Domenic Luongo at 240-370-4314 or **luongo@oakland.edu**

It is the Principal Investigator's (applicant) responsibility to ensure that all personnel having contact with the research animals identified in this application has completed **Research Hazards Awareness Training** and has been offered the opportunity to participate in Oakland University's Occupational Health Program for Animal Handlers (Medical Surveillance Program). Research personnel must acknowledge that they have been offered the opportunity to participate by either submitting a completed **Health Review for Animal Handlers Questionnaire Form**, or an **Animal Handlers Declination Form** to the Graham Health Center (GHC). Please list all research personnel including the PI/applicant who will be participating in this project and check the appropriate box next to their name.

Name	Research Hazards Awareness Training Completed	Health Review Questionnaire or Declination Form submitted to Graham Health Center
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]

Appendix 9: IACUC/OB Protocol Form

6. OVERVIEW

a. STUDY GOALS

i. Provide an overall summary of the project.

ii. Describe the specific aims or objectives of the study. If there is more than one objective, state them in numbered sequence.

Use Lay Terms and Language Understandable to a High School Student.
Abbreviations and Acronyms Should Be Spelled Out and Explained.

b. BENEFITS

Explain how the information gained in this study will benefit human or animal health, the advancement of knowledge, and/or serve the good of society.

Use Lay Terms and Language Understandable to a High School Student.
Abbreviations and Acronyms Should Be Spelled Out and Explained.

7. ANIMAL REQUEST

Include, if appropriate, all animals to be used for breeding purposes only, including those culled and used (numbers must match those listed in Appendix C)

IF ANY ANIMALS ARE IN PAIN CATEGORY D OR E, YOU MUST ALSO COMPLETE APPENDIX B

GUIDELINES FOR PAIN/DISTRESS CATEGORIES *

Definitions

Pain – Acute: Abrupt in onset, relatively short in duration and generally alleviated by analgesics.

Chronic: Long standing physical disorder or emotional distress that is usually slow in onset, has a long duration, and is generally not totally alleviated by analgesics.

Distress: Undesirable physical or mental stress resulting from pain, anxiety, or fear.

For any one animal, the procedure performed that warrants the most significant pain category determines the pain classification for that animal or group of animals (ex., animals experience tail vein blood draw (C) and then external venous port implant (D) would be listed in pain category D).

Category B – Breeding or housing, only. NO procedures.

Category C - Animals will not experience pain, discomfort or distress for which pain-relieving drugs would customarily be given in human medicine or standard veterinary medicine, e.g., radiography; observations; irradiation; some IV/IP/SQ injections; short, simple exams.
Category D - Animals might experience pain, discomfort or distress, but appropriate anesthetics, analgesics or tranquilizers **will be used** to minimize these effects. (e.g., tail biopsy (for DNA), intracardiac injection, vascular cutdowns, prolonged restraint, debilitating tumor growth, myocardial infarction, all surgery). **Studies falling within pain category D must provide detailed justification in APPENDIX B.**
Category E - Animal might experience pain, discomfort or distress for which anesthetics, analgesics or tranquilizers would customarily be given, but these drugs **cannot be used** because their use would adversely affect the results or interpretation of the study. (E.g. studies of pain, some toxicity tests, death as an end-point study). **Studies falling within pain category E must provide detailed justification in APPENDIX B.**

Investigators should consider that procedures that cause pain or distress in human beings also cause pain or distress in other animals. Contact the Animal Research Facility (ARF) Manager (248-370-4440) for help in selection of pain category, if needed.

Use One Line per Species per Pain Category

Common Name	Strain, Subspecies, or Breed	Total No. for 3 yrs.	Pain Category B, C, D, or E	Age, Wt. or Size at Study Initiation	Sex	List Source: Name of Vendor or Institutional Source	List Source: In-house Breeding (✓)	List Source: Transfer from another project (State IACUC No.)	List Source: Other

8. ANIMAL HOUSING

Animals will be socially housed in accordance with the procedures in the IACUC Policy on Social Housing.

☐ Yes
☐ No: Provide scientific justification to include:

1. Which animals will not be socially housed _____
2. The duration of the exception period _____
3. The specific rationale for the research need for this exception, including references, if available.

_____

Appendix 9: IACUC/OB Protocol Form

Species	Maximum Daily Population	Approximate Duration of Housing Period per Animal	Where Will Animals Be Housed BRSF	Other: State Bldg and Room	Transport of Animals out of BRSF Y or N (if yes, state destination)

9. ANIMAL HUSBANDRY

A. Describe any **special conditions** or handling requirements which are anticipated. Be sure to indicate the need for such things as special cages, housing conditions (e.g., temperature, light cycles, humidity, isolation, etc.), diet, equipment, instruments or supplies. The ARF Manager (248-370-4440) should be consulted to assure that necessary items are available. Provision for special materials not currently available should be made in your research budget.

10. CONTROLLED SUBSTANCES:

Name of drug(s):

Individual responsible for the procurement, use, and storage of the controlled substances.

HAZARDOUS CONDITIONS: Will the project pose any of the following hazards to staff, to passersby or to any animals? If the answer to questions 11, 12, 13, 14, 15 is "YES" you must fill out and submit with this application, the **HAZARDOUS MATERIALS SUPPLEMENT, APPENDIX A**.

11. CHEMICAL HAZARDS: ___ Yes ___ No

12. RADIATION HAZARDS: ___ Yes ___ No

13. BIOLOGICAL HAZARDS: ___ Yes ___ No

14. CREATION, IMPORTATION and/or BREEDING of TRANSGENIC ORGANISMS:

___ Yes ___ No

15. Does the research involve the introduction of human embryonic stem cells and/or human induced pluripotent stem cells into animals?

___ Yes ___ No

If yes, indicate the date of HPSCROC (Human Pluripotent Stem Cell Research Oversight Committee) review and approval. _____/_____/_____ (mm/dd/yyyy)

Appendix 9: IACUC/OB Protocol Form

16. ASSURANCES:

The Public Health Service (PHS) *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (42 CRF 50, Subpart F)* regulation governs the identification and management of conflicts of interest (COI) in research for investigators who receive or apply for funding from agencies of the PHS.

Principal Investigators planning proposal submissions should be proactive in ensuring that *all* individuals responsible for the design, conduct, or reporting of research have completed the required COI training and COI declaration requirements ***before*** the agency proposal submission deadline, as required by the federal regulations.

Researcher's Declaration:

I acknowledge responsibility for this project and all COI requirements. I certify that this project will be conducted in compliance with all applicable policies and procedures regarding the care and use of research animals at Oakland University. I hereby give assurance that:

1. I will obtain IACUC approval **prior to implementing any changes** in this application.
2. I assure that all faculty, staff and students involved in the project **are qualified and trained** to conduct the project in a humane and scientific manner, in accord with the PHS Policy and Animal Welfare Act regulations.
3. This project does not **unnecessarily duplicate previous research or instructional projects.**

Signature of Principal Investigator Date

Signature of Responsible Faculty Member Date
(If PI is not a Faculty Member)

DEPARTMENT CHAIRPERSON'S ASSURANCE (MUST SIGN #1 **OR** #2 BELOW):

1. **INTERNAL REVIEW:** I assure that this project has been reviewed and approved for scientific or instructional merit by:

____My own review ____Designated expert review (give name of reviewer)

_____ _____
Signature of Department Chairperson Date

2. **EXTERNAL REVIEW:** I assure that this project does not require internal review because it will not be commenced until it has been reviewed favorably by:

Name of Agency:

_____ _____
Signature of Department Chairperson Date

Appendix 9: IACUC/OB Protocol Form

PART II **Species_____**

Complete a separate copy for each species. If you have more than one species, complete additional copies of Part II and attach to your RAM application.

17. SCIENTIFIC JUSTIFICATIONS

Federal policy, as well as ethical principles, incorporates two goals: 1) live animal use should be minimized, and 2) pain and distress should be reduced to the minimum necessary to obtain valid data. Federal regulations direct the Institutional Animal Care and Use Committee to review proposals to ensure that investigators incorporate these principles into their research. Potential sources for the information needed to complete this section include the National Agricultural Library and the National Library of Medicine.

A. Justification for Live Animals. Describe the alternatives to the use of live animals that have been considered (e.g., in vitro systems, mathematical or computer models, etc.) and why they cannot be used to obtain the desired data.

B. Justification for Choice of Species (Species chosen should be lowest possible phylogenetic species)

____ The results will be directly applicable to the health, care or study of this species.

_____This is a new model. (Cite relevant information//literature describing how this determination was made.)

____ This model has previously been used. Provide citation and an electronic copy of article.

C. Justification for Numbers. Check all that apply and answer subsequent questions.

____ Pilot study or preliminary project, group variances unknown at present. Explain justification.

____ Group sizes based on quantity of harvested cells or amount of tissue required. Explain how much tissue is need based on the number of experiments you will conduct and how much tissue you expect to obtain from each animal. (NOTE: "The study requires 50 experiments" is not sufficient,)

____ Group sizes determined statistically. What statistical analysis was performed?

____ Other. Indicate criteria used to determine (NOTE: "This is the number used in previous studies" is not sufficient.)

Appendix 9: IACUC/OB Protocol Form

( ) IF ALL ANIMAL PROCEDURES ARE TO BE PERFORMED AFTER EUTHANASIA ONLY, CHECK HERE AND PROCEED TO QUESTION 19.

18. PROCEDURES

Note Regarding Use of Non-Pharmaceutical Grade Drugs: Investigators should use pharmaceutical grade medications whenever they are available; including anesthetics, analgesics, test substances, etc. Cost savings alone are not an adequate justification for using non-pharmaceutical grade compounds in animals. (http://www.aphis.usda.gov/ac/policy/policy3.pdf).

Note Regarding Breeding: If you are breeding animals as part of this project, you must complete APPENDIX C.

A. Describe each procedure in chronological order. Committee members should be able to follow the progression of events from experimental initiation to completion.
   - If an individual animal or subset of animals will be used in only one procedure, state as such and identify these animals (as they relate to Part1, #7).
   - If an individual animal or subset of animals will be used in more than one procedure or series of procedures, identify which animals (as they relate to Part 1, #7) and describe the procedures according to chronology, frequency of procedures, and interval between procedures.

B. Please specify the following information.
   a. **Substances Administered. Do not list anesthetics or analgesics here. Another chart is provided specifically for them. List all substances by their generic name. Provide trade names if it is relevant to their use.**

Substance	Dosage	Route of Administration	Volume	Site on the Animal	Frequency

b. Methods of Restraint (e.g. physical, chemical) and duration.

NOTE: If prolonged, conscious physical restraint greater than thirty (30) minutes is required, you must complete APPENDIX D. Physical restraint is defined in the *Guide* as "…the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Animals are restrained for brief periods, usually minutes, in most research applications. Animals can be physically restrained briefly either manually or with restraint devices. Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal."

c. For Non-Surgical or Minor Surgical Procedures: (Minor Surgical Procedures may include procedures similar to those performed on humans in an outpatient clinical setting.)
   a. Anesthetics and/or analgesics. **List all anesthetics and analgesics by their generic name. Provide trade names if it is relevant to their use.**

Anesthetic/Analgesic	Dosage	Route of Administration	Volume	Site on the Animal	Frequency

b. Potential study induced or phenotypic related issues the animal may experience. Consider: changes in appearance ocular discharge, swellings, tumors [cannot exceed 10% of body weight]; changes in respiration, changes in appetite; changes in weight [cannot exceed decreases greater than 10%]; other changes such as muscle atrophy, blindness, infection, etc. Comment on any issues that may change the animal's ability to behave or function prior to the procedure, as well as how these will be monitored and addressed.

Appendix 9: IACUC/OB Protocol Form

IF PROCEDURES WILL INCLUDE MAJOR SURGERY (e.g. entry into a body cavity), YOU MUST COMPLETE APPENDIX E FOR EACH SPECIES.

19. EUTHANASIA: What method of euthanasia will be used?

Method: ___CO_2 Overdose ___Drug Overdose __Other (Explain)
If drug overdose:
Name of drug:
Route:
Dosage:

Note: Proficiency at cervical dislocation for euthanasia must be verified by the ARF Manager. If intracardiac injection is used, animal must be sedated prior to injection.

20. METHOD OF ASSURANCE OF DEATH: Death must be assured by means other than an overdose of drug or gas alone.

___ bilateral pneumothorax ___ transection of the aorta ___ cervical dislocation

___ Other, explain:

21. TRANSFER ARRANGEMENTS: At the conclusion of this project, if there are surviving animals, indicate your preference as to the final disposition of these animals. **NOTE: All animal transfers/ donations to other approved projects must be approved by and coordinated through the ARF Manager.**

APPENDIX A

OAKLAND UNIVERSITY

APPLICATION TO USE VERTEBRATE ANIMALS IN RESEARCH, TEACHING OR TESTING

HAZARDOUS MATERIALS SUPPLEMENT

NOTE: It is the Principal Investigator's Responsibility to Insure That All Individuals Who May Come in Contact with a Project are Aware of Any Hazards Involved in the Project.

A. Does this application have an approved Institutional Radiation Safety Committee (IRSC) application?

Yes ___ No ___ Submitted Pending Approval___

If yes, attach a copy of the application and include Approval Date: _____

Does this application have an approved Institutional Biosafety Committee (IBC) application?

Yes ___ No ___ Submitted Pending Approval ___

If yes, attach a copy of the application and include Approval Number: _____

Work cannot begin until all regulatory compliance committee applications associated with this AUVA have been approved by the governing committees and a copy of the approved application is submitted to the Animal Research Facility Manager.

B. CHEMICAL HAZARDS:

Agent(s) or Chemical(s):
Route(s) of administration:
Dosage(s):
Route(s) of excretion:
Is (are) the agent(s) or chemical(s) known or suspected carcinogens? ___ Yes ___ No

C. RADIOISOTOPES:

Isotope(s) and activity level:
Principal chemical formula:
What is the half-life period?:
Route(s) of excretion:

D. BIOHAZARDS:

Infectious agent(s):
Route(s) of administration:
Dosage(s):

Indicate species at risk and virulence of agent(s):

E. CREATION, IMPORTATION AND/OR BREEDING OF TRANSGENIC ORGANISMS:

Is IBC approval needed for the purchase, maintenance, or transfer of the transgenic animals?

Yes ___ No ___ Submitted Pending Approval ___

If yes, attach a copy of the application and include Approval Number: _____

PREVENTION: DANGERS - HAZARDS - Describe measures that will be taken to minimize the risks from all hazards indicated in this section. Specify the procedures that will be used to decontaminate equipment prior to routine washing

Appendix 9: IACUC/OB Protocol Form

APPENDIX B **Species _____**

COMPLETE THE FOLLOWING SECTION FOR ALL ANIMALS IN PAIN CATEGORIES D OR E
(See PART I, Number 7)
COMPLETE A COPY OF THIS SECTION FOR EACH SPECIES

NOTE: If use of animals in ***Categories D*** or ***E*** is planned, PI **MUST** consult the ***Attending Veterinarian*** or his/her designee prior to submitting the application: penman@oakland.edu

Date of consultation with the Attending Veterinarian? _____

A. Federal regulations and university policy require consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals. The intent of the questions is to evaluate the consideration of procedures or parts of procedures that will produce the least amount of pain or discomfort – the 3R's: Replacement, Reduction, Refinement. Note: Any procedure requiring anesthesia is a painful procedure.

1. Explain why you cannot ***REPLACE*** your choice(s) of species with a lower species. (e.g., *in vitro* models, computer models, less sentient animals).

2. Explain why you cannot ***REFINE*** your experimental procedures further to minimize pain and distress. (e.g., early endpoints; use of anesthetics and/or analgesics, techniques to reduce stress).

3. Explain why you cannot ***REDUCE*** the number of animals needed further than what you have specified (e.g., appropriate statistical methods, reduction in experimental variability by using defined genetic status, sharing tissue among investigators).

B. Methods used to search for alternatives for the availability or appropriateness of the use of less pain or distress-inducing procedures, less invasive procedures, or in-vitro methods. Indicate all that apply.

1. Literature search conducted. More than one database search is required, (such as; AAGRICOLA, Medline, PubMed, Altweb (http://altweb.jhsph.edu/databases/databases.htm), AWIC (www.nal.usda.gov/awic). When a database search is the primary means of meeting this requirement, the narrative must, at a minimum, include all of the following:
   a. The names of the databases searched;

   b. The date the search was performed;

   c. The period covered by the search;

d. The key words and/or the search strategy used; include key words applicable to materials, methods or procedures that may be related to pain or distress, as well as disease or animal model used.
Include/use these same keywords as part of the search criteria when filling out the Annual Review of Approved Projects Form.

2. Consultation with colleagues, specific to alternatives to animal use, pain, distress.
   a. Name and qualifications:

   b. Date and Content of consult:

3. Other: Provide a detailed explanation.

C. For any animals in pain Category E, provide a detailed explanation and justification for the procedures and for not using appropriate alternatives. This information will be reported to the USDA and is available under the Freedom of Information Act.

Appendix 9: IACUC/OB Protocol Form

APPENDIX C **Species _____**

Oakland University
BREEDING PROTOCOL

1. Please provide a justification for the need for breeding (e.g., animals are not commercially available, in utero studies, breeding studies, etc.). NOTE: The cost of commercially available animals is not justification.

2. List the species and strains of animals to be produced in the breeding program

3. A. Total number of animals expected to be produced (used and culled) in this study as a result of breeding. _____
   i. Yearly total _____
   ii. 3-Year total _____

   B. Breeding stock replenishment
   ii. Yearly total _____
   ii. 3-Year total _____

4. What will be done with the surplus animals? NOTE: Transfers to other approved studies are to be coordinated through the ARF Manager.

5. DNA/transgene or gene to be disrupted:

6. Are there any inherent problems for the animal associated with the transgenic line itself? If yes, explain.

7. Method of monitoring presence of transgene in the animals.

8. Describe any special care or monitoring that may be required for these animals.

9. How long will these founders/breeders be maintained?

10. What is the final disposition of the founders/breeding colony?

11. What are the criteria for euthanasia for these founders/breeders?

APPENDIX D

Species _____

CONSCIOUS, PROLONGED PHYSICAL RESTRAINT

Physical restraint is defined in the Guide as "…the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Animals are restrained for brief periods, usually minutes, in most research applications. Animals can be physically restrained briefly either manually or with restraint devices. Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal."

IF AN ANIMAL IS TO BE SUBJECTED TO CONSCIOUS PHYSICAL RESTRAINT FOR THIRTY (30) MINUTES OR LONGER, THIS FORM MUST BE COMPLETED.

1. Describe method, device.

2. Describe how animal will be acclimated.

3. State the frequency of restraint.

4. State the duration the animal will be confined.

5. Describe observation and monitoring procedures, and how animal will be assessed during restraint.

6. Describe criteria to be used for release from restraint.

Appendix 9: IACUC/OB Protocol Form

APPENDIX E

Species _____

COMPLETE A SEPARATE COPY OF THIS SECTION FOR EACH SPECIES

NOTE: Regarding Surgeries:
All surgeries must be performed using aseptic techniques.
All rodent survival surgeries must be performed in a designated area approved by the IACUC.
All non-rodent mammal surgeries must be performed in a dedicated surgical area.

1. State name of the surgeon and experience with the species and surgical procedure.

2. Specify anesthetics and/or analgesics. (e.g., dosage, volume, sites, frequency, and how anesthetic level will be monitored).

3. NOTE: If neuromuscular paralytics are to be used, provide detailed information as to which physiological parameters will be monitored, the variances which will be tolerated, and the steps to be taken if any parameter varies outside of the expected range.

4. Describe specifics to the surgery such as approach, operative procedures, closure and recovery.

5. Describe postoperative care, including analgesics, antibiotics and monitoring of fluids and body temperature.

6. Describe potential surgery induced or phenotypic related issues the animal may experience. Consider: changes in appearance (ocular discharge, swellings, tumors [cannot exceed 10% of body weight]; changes in respiration, changes in appetite; changes in weight [cannot exceed decreases greater than 10%]; other changes such as muscle atrophy, blindness, infection, etc). Comment on any procedures that may change the animal's ability to behave or function prior to the procedure, as well as how these will be monitored and addressed.

7. How long will animals be maintained after surgery?

8. Multiple major survival surgeries are discouraged. If animals will undergo more than one major survival surgery, provide an appropriate scientific justification.

Appendix 9: IACUC/OB Protocol Form

Oakland University
Institutional Animal Care and Use Committee
Annual Review of Approved Projects

This form is necessary to remain in compliance with Oakland University's Institutional Animal Care and Use Committee (IACUC) continuing review of each previously approved project as required by Federal law.

All Principal Investigators with projects approved by the IACUC, who have a project approval period greater than one year, must complete and submit an Annual Review of Approved Projects form.

Failure to submit an accurately completed Annual Review of Approved Projects form to the IACUC Administrator, Office of Research Administration, 104 BRSF (Biomedical Research Support Facility), will result in withdrawal of IACUC approval and suspension of any future work on the project.

IACUC Project Approval #: Date of Annual Review:

IACUC Project Approval Period: to

Project Title:

Project Period: to

Principal Investigator:

PLEASE RESPOND TO ALL OF THE FOLLOWING:
What is the status of the above referenced project?

☐ Active ☐ Inactive ☐ Completed ☐ Never Initiated

A. Note all progress made on achieving stated specific aims of this project. _____
_____

B. Note all adverse complications and their resolution. _____
_____

C. Specify the funding source. _____

D. Animals will be socially housed in accordance with the procedures in the IACUC Policy on Social Housing.
(See Part I, Item 8, Animal Housing, approved in the original application)

☐ Yes
☐ No: Provide scientific justification to include:

4. Which animals will not be socially housed _____
5. The duration of the exception period _____
6. The specific rationale for the research need for this exception, including references, if available. _____
_____

Appendix 9: IACUC/OB Protocol Form

E. Conduct a new literature search to address the following: **This new literature search is required of all animal use in pain categories D or E.**

1. Have any new alternatives to the use of animals become available that could be used to achieve your specific project aims? _____
   State the search criteria used. (key words, data base searched, publications, conferences, and dates) **as part of the search criteria, include and use the same key words that were used and approved in the original application. See Appendix B of the original AUVA.** _____

2. Have any new alternatives to painful or distressful procedures become available? _____
   State the search criteria used. (key words, data base searched, publications, conferences, and dates) **as part of the search criteria, include and use the same key words that were used and approved in the original application. See Appendix B of the original AUVA.** _____

F. If significantly fewer animals have been used within in the last year than originally proposed provide an explanation. _____

G. What is the projected animal use for the next one-year period? _____

☐ Check here, if there have been no changes to the currently approved protocol and this form is to be used to request approval for a one year continuation of the IACUC project.

☐ Check here, if changes are proposed. You must identify any and all changes on the appropriate page(s) of your approved application form, indicate "Revised (date)" at the top, and submit the revised application in RAM 3.0.

Name	CITI Program Training	
	1. Working with Animals in Biomedical Research – Basic Course	1. Working with Animals in Biomedical Research – Refresher Course
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]
	[ ]	[ ]

Reminder: The "Final Rule" regarding financial conflicts of interest in PHS-funded research went into effect 8/24/2012. The Final Rule requires all investigators engaged in or planning to engage in PHS-funded research to disclose ***all personal significant financial interests (SFI)*** related to the Investigator's institutional responsibilities. This requirement also includes the financial interests of each investigator's spouse and/or dependent children.

If your study is PHS funded and includes any personnel on the project that meets the PHS definition of "investigator," you must contact the Office of Research Administration to submit a Significant Financial Disclosure Form. ***Investigators*** are defined as all individuals who are responsible for the design, conduct or reporting of the PHS-funded work. See OU's research policy and operational guidance on compliance with the FCOI Final Rule at http://wwwp.oakland.edu/research/compliance/

Appendix 9: IACUC/OB Protocol Form

Signature of Principal Investigator: _____ Date: _____

Signature of Department Chairperson: _____ Date: _____

Approved by: _____ _____

IACUC Chairperson Attending Veterinarian

************OFFICE USE ONLY************

Species	Number Approved to Use	Number Used	From	To	Total Used to Date

Appendix 9: IACUC/OB Protocol Form

IACUC Amendment for Addition of Personnel

Instructions: Send/deliver the signed original request form to the IACUC Administrator, 104 BRSF. Laboratory personnel added to a protocol cannot work with live animals until an amendment has been approved by the IACUC Chair and the Animal Research Facility Manager. Questions can be directed to (248) 370-4440 or schofdin@oakland.edu

IACUC PROTOCOL NUMBER(S): _____

PRINCIPAL INVESTIGATOR: _____

EMAIL: _____

PHONE: _____

DEPARTMENT: _____

1. List personnel who will be added and contact information.

Name and Degree	Home Telephone Number	OU Office/Lab Phone Number	Cell Phone Number	E-mail Address

Previous Experience and Responsibilities for this Protocol - Identify the responsibilities of each individual, and his/her experience with the procedures and the animal species. Use the following categories for function: 1-Euthanasia; 2-Anesthesia; 3-Surgery, 4-Postoperative care, 5-Nonsurgical Procedures, 6-Handling or Restraint of Animals, 7-Other (Explain).

2.

			Years of Experience		
Name and Degree	**Species**	**Specific Function in Project**	**With this species**	**With these procedures**	**With survival surgery (if applicable)**

Appendix 9: IACUC/OB Protocol Form

3. The following Research Personnel should be deleted from the protocol(s):

Name:
Name:

As principal investigator I certify to the following:

1. My staff and I will comply with all standards for animal care and investigation established in the *Guide for the Care and Use of Laboratory Animals* (8th Edition, 2010) and the Federal Animal Welfare Act, and will follow all policies established by the University to assure that these standards are met.

2. All individuals working with the animals on this protocol are qualified by virtue of training or experience to perform proper handling, experimental, and restraint techniques required for the species to be used.

Principal Investigator Signature:	**Date:**

Reminder: The "Final Rule" regarding financial conflicts of interest in PHS-funded research went into effect 8/24/2012. The Final Rule requires all investigators engaged in or planning to engage in PHS-funded research to disclose *all personal significant financial interests (SFI)* related to the Investigator's institutional responsibilities. This requirement also includes the financial interests of each investigator's spouse and/or dependent children. If your study is PHS funded and includes any personnel on the project that meets the PHS definition of "investigator," you must contact the Office of Research Administration to submit a Significant Financial Disclosure Form. *Investigators* are defined as all individuals who are responsible for the design, conduct or reporting of the PHS-funded work. See OU's research policy and operational guidance on compliance with the FCOI Final Rule at http://wwwp.oakland.edu/research/compliance/

Training Requirements: All laboratory personnel must complete the appropriate training before working on an animal protocol. The IACUC Administrator will verify training for personnel; ALL training is required prior to approval.

EACH INDIVIDUAL HAS TO TAKE Collaborative Institutional Training Initiative (CITI) Program Courses **www.citiprogram.org**

- **Working with Animals in Biomedical Research – Basic Course**
  Please inform personnel to not mistakenly sign up for, Working with Animals in Biomedical Research - Refresher Course. The Refresher Course needs to be completed three (3) years after the Basic Course. CITI will automatically send you an email when it is time to complete the Refresher Course.

- **Working with (Species-specific to whatever species you will be working with on the project**
  (i.e. "Working with Rats in Research Settings", Working with Mice in Research Settings", etc.)

Appendix 9: IACUC/OB Protocol Form

OAKLAND UNIVERSITY

IACUC Amendment to Add or Change Source(s) of Animals

Instructions: Send/deliver the signed original request form to the IACUC Administrator, 104 BRSF, Oakland University
Questions can be directed to: (248) 370-4440 or schofdin@oakland.edu

Purpose of Form:
This form is designed to aid the PI and the IACUC in documenting and tracking changes in source of animals that are to be used in the currently approved IACUC protocol.

IACUC PROTOCOL NUMBER: _____

PRINCIPAL INVESTIGATOR: _____

EMAIL: _____

PHONE: _____

DEPARTMENT: _____

Original Source of Animals	Species	Vendor Name/Address

New or Additional Source of Animals	Species	Vendor Name/Address

Reason for the addition of change of source of animals.

Principal Investigator Signature:	Date:

Appendix 9: IACUC/OB Protocol Form

IACUC Amendment to Add or Change Source(s) of Grant Funding

Instructions: Send/deliver the signed original request form to the IACUC Administrator, 104 BRSF, Oakland University

Questions can be directed to: (248) 370-4440 or schofdin@oakland.edu

Purpose: The IACUC has developed procedures for verifying that the IACUC has reviewed and approved all animal subject research related activities associated with externally funded proposals. Investigators should note that monies will not be released unless the grant application has been reviewed and compared to the IACUC protocol.

Oakland University's Public Health Service (PHS) assurance states that the institution is guided by the same ethical principles and procedures regarding all research involving animals regardless of funding agency. The signature of an authorized Institutional Official (IO) on applications for funding indicates the institution's intent to comply with the laws, regulations, and policies to which a funded project is subject, including applicable public policy requirements. The IO is also attesting to the fact that the information contained in the application is true and complete, and conforms with federal requirements and the institution's own policies and requirements. The signatures on these application forms, for both the Principal Investigator (PI) and the IO, also make it very clear that there are potential civil and criminal penalties for submitting false statements or claims.

Purpose of Form:

This form is designed to aid the PI and the IACUC in documenting and tracking changes in sources of funding associated with the currently approved IACUC protocol.

IACUC PROTOCOL NUMBER:

PRINCIPAL INVESTIGATOR: _____

EMAIL: _____

PHONE: _____

DEPARTMENT: _____

Appendix 9: IACUC/OB Protocol Form

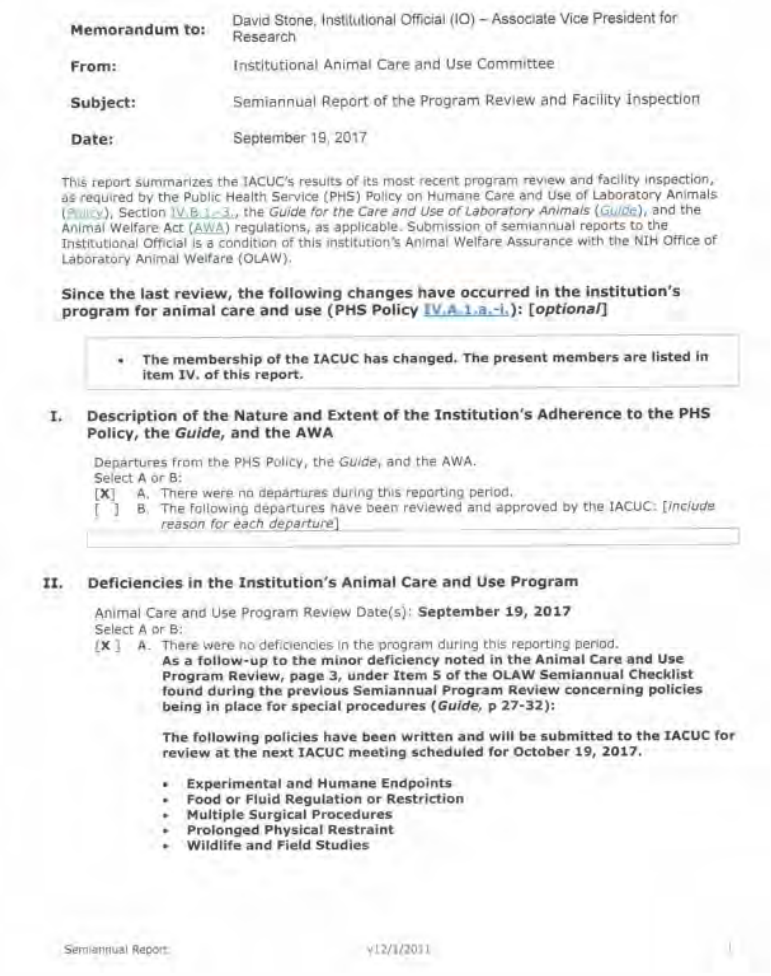
Original Funding Agency	Grant Number	Account Number
New Funding Agency	**Grant Number**	**Account Number**
New Grant Title (if applicable)		

Summary of scope of work or research activity supported by change of Funding Agency

Does this change affect your research activities in the currently approved IACUC protocol?	
☐ Yes, please explain the effect of the change	☐ No
Principal Investigator Signature:	Date:

Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.



Memorandum to: David Stone, Institutional Official (IO) – Associate Vice President for Research

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: September 19, 2017

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

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

- **The membership of the IACUC has changed. The present members are listed in item IV. of this report.**

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

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

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

Animal Care and Use Program Review Date(s): **September 19, 2017**
Select A or B:
[X] A. There were no deficiencies in the program during this reporting period.
As a follow-up to the minor deficiency noted in the Animal Care and Use Program Review, page 3, under Item 5 of the OLAW Semiannual Checklist found during the previous Semiannual Program Review concerning policies being in place for special procedures (*Guide*, p 27-32):

The following policies have been written and will be submitted to the IACUC for review at the next IACUC meeting scheduled for October 19, 2017.

- **Experimental and Humane Endpoints**
- **Food or Fluid Regulation or Restriction**
- **Multiple Surgical Procedures**
- **Prolonged Physical Restraint**
- **Wildlife and Field Studies**

Semiannual Report v12/1/2011

[ ] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency. deficiencies may be recorded on a separate table and attached. the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): **July 31, 2017**

Select A or B:

[ ] A. There were no deficiencies in the animal facility during the reporting period.

[X] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency. deficiencies may be recorded on a separate table and attached. the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]

A minor deficiency was found [redacted]

A tube of ophthalmic ointment was found [redacted] **without an *expiration date. It was noticed* that the manufacturer of the product has stopped stamping the expiration dates directly on the tubes, and is only stamping the outside of the box the tubes are packaged in. The attending veterinarian advised disposing of the opened tube, since it is unclear what the actual expiration is without having the original box it was packaged in. Going forward, BRSF personnel will be directed to *write* the expiration dates directly on the tubes with permanent marker, once they *are* taken from their original packaging.**

IV. Minority Views

Select A or B:

[X] A. No minority views were submitted or expressed.

[ ] B. The following minority views were expressed: [insert minority views here or attach]

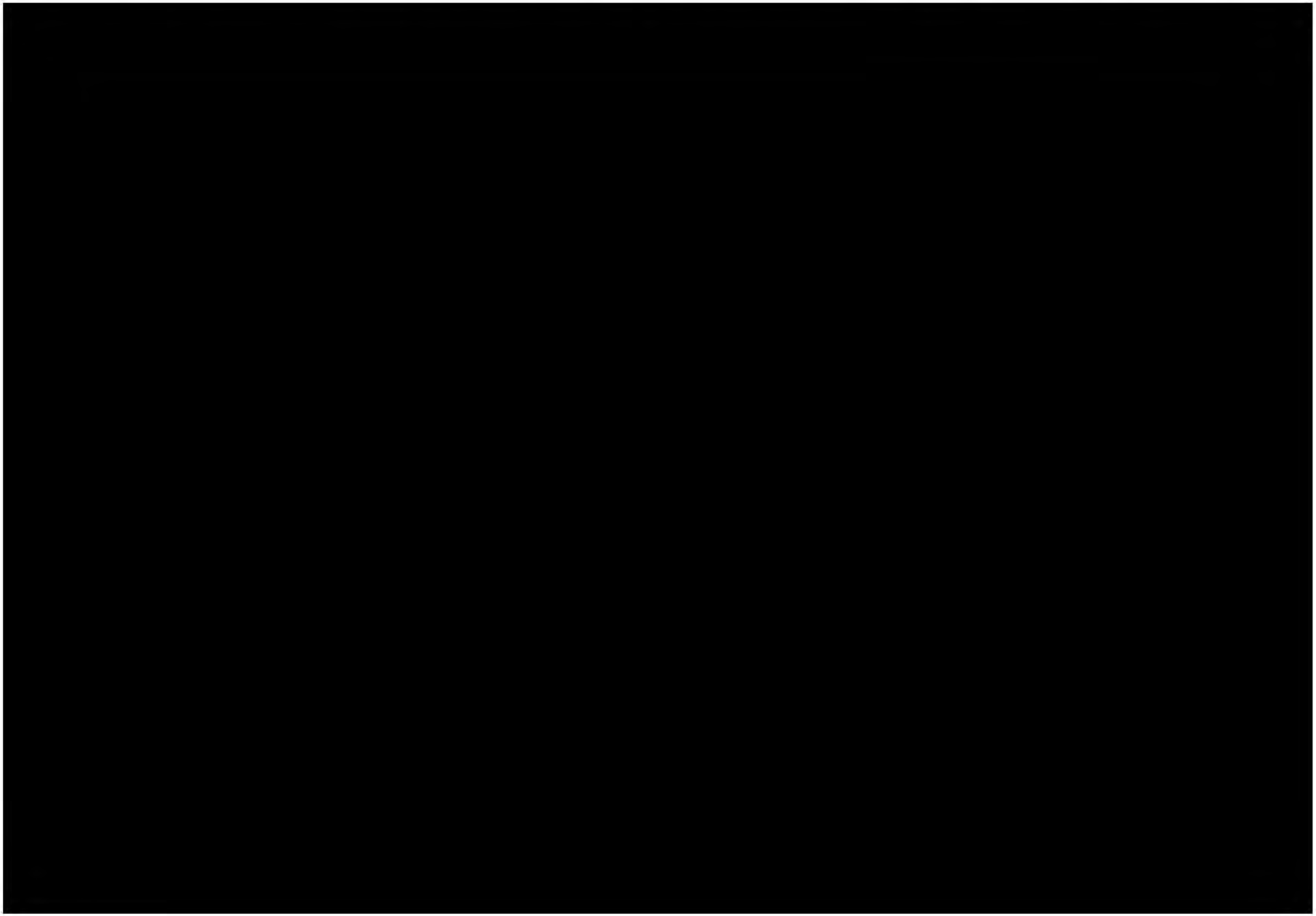
V. Status of AAALAC Accreditation [identify accredited facilities, if applicable]

CONTINUED FULL ACCREDITATION as of June 8, 2015

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

Names of IACUC Members	Signatures
Keith Williams, Ph.D., Chair	
Amy Barnes-Bancroft, Ph.D., Vice Chair and Scientist Member	
Lori Penman, D.V.M., Attending Veterinarian	
Louis Miller, M.S., Community Representative	
Janet R. Schofield, Mgr. BRSF, Member	
Jamie Nugent, Ph.D., Nonscientist Member	
Dao-Qi Zhang, Ph.D., Scientist Member	
Claudio Cortes, Ph.D., Scientist Member	

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

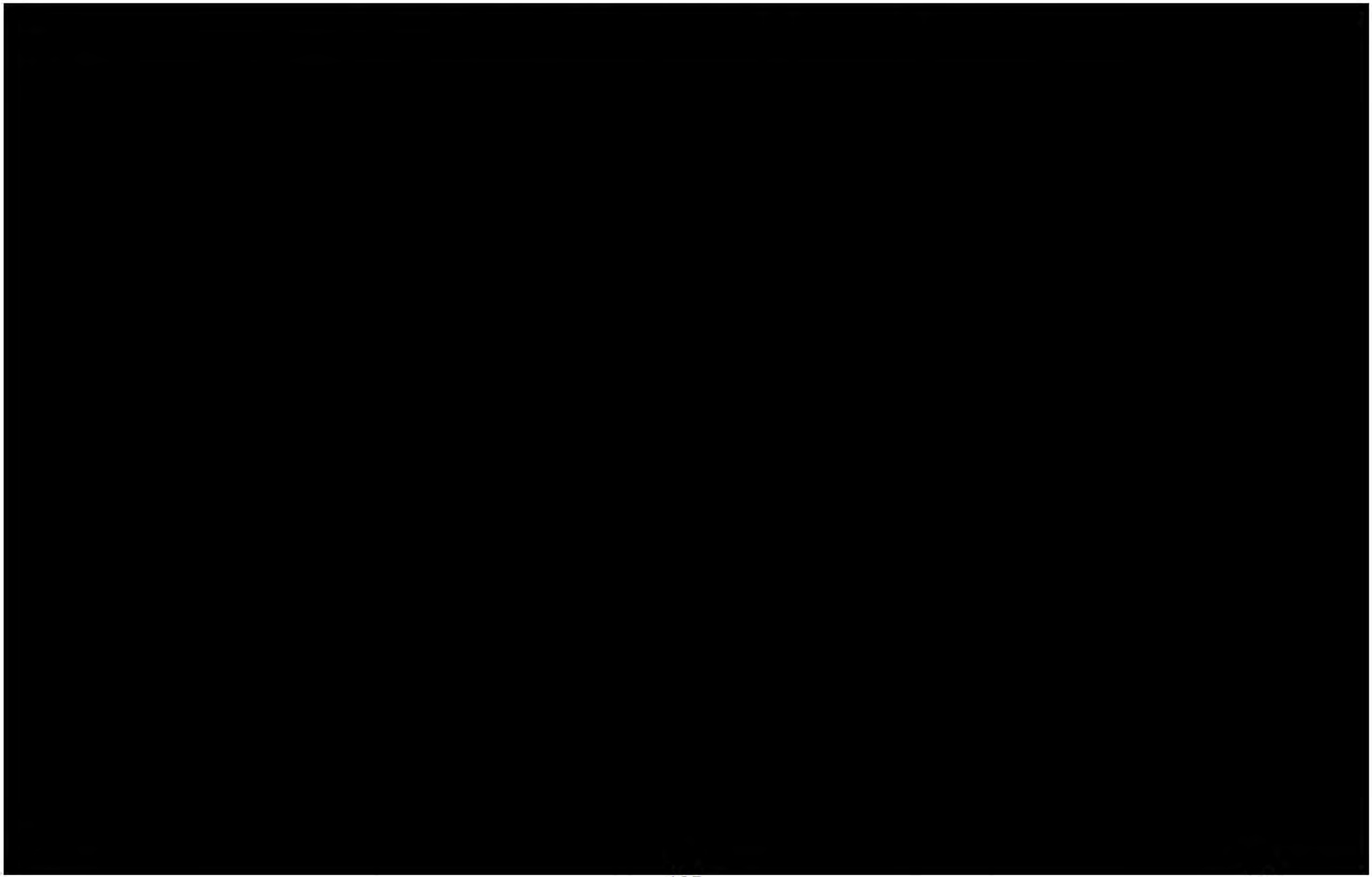


Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

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

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

Appendix 12: Aquatic Systems Summary – Part I



Appendix 12: Aquatic Systems Summary – Part II

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mouse	6.5" X 10.5" X 5"h = 68.25 in^2	< 10 grams up to 11/cage > 25 grams up to 4/cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate shoebox suspended on a rack
Mouse	7" X 11" X 5"h = 77 in^2	< 10 grams up to 11/cage > 25 grams up to 4/cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate static micro-isolator
Mouse	7.5" X 8.5" X 8"h = 63.75 in^2	< 10 grams up to 10/cage > 25 grams up to 4/cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate shoebox suspended on a rack
Mouse	8.5"" X 17" X 6"h = 144.5 in^2	> 25 grams up to 9/cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate with wire lid
Rat	8.5" X 17" X 8"h = 144.5 in^2	< 100 grams up to 9/cage > 401 grams up to 2/cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate shoebox suspended on a rack or with wire lid
Guinea Pig	8.5" X 17" X 8"h = 144.5 in^2	> 350 grams up to 1/cage larger guinea pigs will require more space	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate shoebox suspended on a rack
Guinea Pig	15" X 22" X 8"h = 330 in^2	One/Cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate with wire lid

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**
Guinea Pig	14.5" X 18.5" X 9"h = 268.25 in^2	One/Cage	*Guide for the Care and Use of Laboratory Animals*	Direct bedding polycarbonate with wire lid
Frog or Tadpoles	Static housing freestanding tanks	1 adult frog/liter with no more than 4 frogs/5.5 liter tank Tadpoles are maintained at a density of no more than 25/liter	*The Laboratory Xenopus sp.*, by Sherril L. Green CRC Press *The Guide of Xenopus Express* http://www.xenopus.com/husbandry.htm	5.5 liter rigid plastic tank An environmental incubator maintains temperature and light cycles. A complete change of water is done 3 times a week.

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Micro-environment				
Solid-bottom cages (static)	Mechanical Washer	Weekly	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Solid-bottom cages (IVC)	Not Applicable			
Suspended wire-bottom or slotted floor cages	Not Applicable			
Cage lids	Mechanical Washer	Every 2 weeks	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Filter tops	Mechanical Washer	Monthly	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Cage racks and shelves	Mechanical Washer	Every 2 weeks	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Cage pans under suspended cages	Not Applicable			
Play pens, floor pens, stalls, etc.	Not Applicable			
Corrals for primates or outdoor paddocks for livestock	Not Applicable			
Aquatic, amphibian, and reptile tanks and enclosures	Hand Washed	As needed per water quality	Goldberg - Not Applicable Raffel - rinsing overnight in a dilute (~1%) bleach or potassium permanganate solution and then rinsed in water with a dechlorinating agent	
Feeders	Mechanical Washer	Weekly	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Watering devices	Mechanical Washer	Weekly	Alkaline Detergent Acid Neutralizer	

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)
			Acid Descaler–Citric Acid Based	
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical Washer	At cage change	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Transport cages	Cages used in transport are run through the mechanical washer	After each use	Alkaline Detergent Acid Neutralizer Acid Descaler–Citric Acid Based	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Hand Washing	Weekly	Bleach	
Euthanasia chambers	Hand Washing	After each use	Quaternary Ammonium Compound	Only if animal is placed directly in the chamber
Macro-Environment				
Animal Housing Rooms:				
Floors	Mopped	Weekly	Quaternary Ammonium Compound	Occupied animal housing rooms only
Walls	Hosed		Quaternary Ammonium Compound	Complete disinfection between animal species or every 6 months
Ceilings	Wiped		Quaternary Ammonium Compound	Complete disinfection between animal species or every 6 months
Ducts/Pipes	Wiped	Weekly	Quaternary Ammonium Compound	
Fixtures	Wiped	Weekly	Quaternary Ammonium Compound	
Corridors:				
Floors	Swept/Mopped	Weekly	Quaternary Ammonium Compound	
Walls	Wiped	Annually	Quaternary Ammonium Compound	
Ceilings	Wiped	Annually	Quaternary Ammonium Compound	
Ducts/Pipes	Wiped	Annually	Quaternary Ammonium Compound	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Fixtures	Wiped	Annually	Quaternary Ammonium Compound	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mopped	Every 6 months	Quaternary Ammonium Compound	
Walls	Wiped	Annually	Quaternary Ammonium Compound	
Ceilings	Wiped	Annually	Quaternary Ammonium Compound	
Ducts/Pipes	Wiped	Annually	Quaternary Ammonium Compound	
Fixtures	Wiped	Annually	Quaternary Ammonium Compound	
Implements (note whether or not shared):				
Mops	Each occupied animal housing room has an assigned mop	Rinsed after use and laundered monthly	Quaternary Ammonium Compound	
Mop buckets	Each occupied animal housing room has an assigned bucket	Rinsed after use run through mechanical washer at room decontamination	Quaternary Ammonium Compound	
Aquaria nets	Hand washed	Before being re-used	Potassium permanganate	
Other				
Other:				
Vehicle(s)	Not Applicable			
Other transport equipment (list)	Not Applicable			

*Please provide chemical, not trade name.

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

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

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
[redacted]	[redacted]	Rack washer Pass-through	Emergency "off" button; labeled exit doors, de-energizing cord on both sides, instructional signage	180-degree hot water rinse; temperature-sensitive tape used weekly; ATP-based luminescence swabs performed monthly
		Tunnel washer Pass-through	Emergency "off" button; de-energizing cord on both sides, instructional signage	180-degree hot water rinse; ATP-based luminescence swabs performed monthly
		Bulk autoclave Pass-through	instructional signage	When in use: Biological indicator run monthly; S.M.A.R.T. Test run monthly; Autoclave indicator tape, bags or strips used each cycle.
		Bulk autoclave Pass-through	instructional signage	When in use: Biological indicator run monthly; S.M.A.R.T. Test run monthly; Autoclave indicator tape, bags or strips used each cycle.

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

Appendix 16: Lighting Summary

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

Location: [redacted]

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

Room Type[a]	Light Intensity Range	Lighting Fixture Construction Features[b]	Photo-period (hrs)[c]	Photoperiod and Lighting Control	Override Mechanisms (if applicable)
Animal Housing Rooms	140 - 525 lux	Surface mounted fluorescent lighting, water resistant	12:12	The light cycles are controlled by Edstrom Industries' Watchdog computer and monitored 24 hours a day. Currently, all but one of the animal housing rooms are on a 12 hour on/12 hour off light cycle. One of the animal housing rooms is on a reversed 12:12 light cycle, due to it being a behavioral study	Manual override Hi/Lo light intensity feature in 20-minute increments when needed to insure adequate and sufficient illumination for the inspection and care of the animals and their environment. Automatic email alarm notification,>30 minutes if lights fail to turn off or on as programmed.
Surgery Rooms	800 – 3000 lux	Arm-mounted and recessed fluorescent lighting, water resistant	N/A	N/A	N/A
Necropsy Room	500 – 900 lux	Recessed fluorescent lighting, water resistant	N/A	N/A	N/A
Clean Cage-Dirty Cage Processing Rooms	300 – 1350 lux	Recessed fluorescent lighting, water resistant	N/A	N/A	N/A
302 DH	110 – 575 lux	Surface mounted fluorescent lighting, water resistant	12:12	12 hour on/12 hour off light cycle	Manual override
302 MSC – Cold Room	110 – 450 lux	Hanging fluorescent	N/A	N/A	N/A

[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**).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft^2 or m^2) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes
[redacted]	[redacted]	[redacted]	Amphibian	155 $feet^2$	7-10 Days 2 months – 8 months	Dedicated cold room with temperatures maintained at 2-3°C. for study purposes	White aluminum casing – walk in refrigerator room
			Amphibian	720 $feet^2$	Up to a year or more depending on the needs of the study	Housing/work space required for study purposes	Floors – poured concrete with floor drains Walls- beige ceramic brick and mortar

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

Appendix 18: Food and Fluid Regulation or Restriction

Presently there are four protocols that involve food and fluid regulation. All four protocols are behavioral studies involving the use of Rats

Protocol Number	Justification	Length and Type of Food/Fluid Restriction	Animal Monitoring Procedures	Methods to Ensure Adequate Nutrition and Hydration
16013-R2	Food and Fluid Restriction - Behavior maintained by the use of a preferred food or fluid reinforcer tends to be high-rate during the initial few minutes of a session, and may decrease to low-rate or disappear as the session progresses. This is related to the observation that food is more reinforcing for food-restricted than sated subjects (see e.g., Epstein et al., 2003, Phys & Beh). Moreover, consumption of a preferred substance under sated conditions is sometimes subject to postingestive alliesthesia, a phenomenon in which previously appetitive stimuli become aversive (see e.g., Cabanac & Lafrance, 1990, Phys & Beh). The proposed studies require that stable rates of behavior be measured for up to 140 min and that the reinforcer continues to maintain behavior for several days, a goal that appears difficult to obtain in subjects receiving ad l b food and water. Depending on the particular study, either food or water will be used as the reinforcer, and no animal will have simultaneous restricted access to both food and water.	Availability of water will be gradually limited to 30 min per day, provided in average 1 h after completion of the daily training sessions. The gradual restriction schedule starts with removal of water bottles overnight (Day 1), and then water access limited to 2 h (Day 2), 90 min (Day 3), 60 min (Day 4), 45 min (Day 5), and 30 min (Day 6 and all subsequent days). If proper hydration is ensured, fluid restriction does not interfere with normal growth and development of young adult rats. Food consumption will be assessed for each cage by subtracting the weight of food remaining from food provided after a 24h period. A gradual 3% decrease in this amount will be imposed on a daily basis, adjusting up or down by 1% depending on the animals' weight change. Once all animals have reached approx. 85% of free-feeding weight, no further reductions in food amounts will be imposed.	Daily communication with the BRSF personnel as well as clearly labeled cages will ensure that BRSF personnel know that protocol personnel is taking care of feeding and watering animals. A feeding/watering log will be prominently displayed in the housing room, including information of time, amount of food/water administered (or whether ad lib), and initials of experimenter providing the food/water (see attached log). Daily checks will include a visual assessment of animal condition (condition of fur and teeth, injuries, bite marks) and bedding (wet and soiled spots are expected). When treatment is provided through drinking water, food/water consumed will be measured on a daily basis to ensure treatment effectiveness and proper nutrition/hydration. Weight checks will be conducted Animals will be checked on a daily basis by the investigators for abnormalities in coat condition (e.g., excessive hair loss or failure to groom), teeth condition (e.g., broken or missing teeth), urine output (i.e., dry bedding), general activity level (e.g., failure to move around cage), and approach to the water bottle when fluid is made available. Rodents consume most of their daily food intake when water is available; thus, animals will be weighed once/week to ensure proper growth and development (note that weight loss is rarely observed in well-hydrated animals).	If an animal exhibits at least one sign of dehydration distress (porphyrin secretions, distress when water bottles are removed, excessive hair loss, lethargy, lack of appetite, loss of skin turgor), it will immediately be separated from its cagemate and given ad lib access to water for 24h, checking for wet spots on bedding twice in the 24h period, and for increased activity and general improvements in body condition at the 24h mark. The distressed animal will be separated from its cagemate(s) during water availability for the remainder of the study. If the animal condition is stable but does not improve within 24h, veterinary assessment will be requested to determine whether supplemental fluids should be administered subcutaneously or intraperitoneally. If animal condition continues to remain poor under ad lib water conditions and/or fluid supplementation, the animal will be considered as having reached a humane endpoint and will be euthanized. Food restriction potentially provides a greater problem in group housing conditions because the time of food availability is not controlled by the experimenter but by the speed with which the animals consume the food. We will feed animals their scheduled food amount, and careful weighing will provide a measure of their food intake. Appropriate weight gain will be assessed against growth curves provided by the vendor for a bino rats. If one of the two animals housed in any given cage exhibits inappropriate weight gain (less than 1 gram of gain/day in juveniles under 14 weeks of age,

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				less than 0.5 grams of gain/day in adults over 14 weeks of age and up to 300 g), the animals will be separated at feeding time, with the leaner animal receiving larger-than-scheduled amounts of chow (at least 5 g extra) until it reaches the expected weight (this usually takes 2-3 days). If appropriate weight gain is not observed after 3 days, the leaner animal will be isolated and placed on an ad lib food schedule for 2-3 days. If the animal continues to fail to thrive, veterinary assessment will be requested
16014	Food and Fluid Restriction - Food and Fluid Restriction - Behavior maintained by the use of a preferred food or fluid reinforcer tends to be high-rate during the initial few minutes of a session, and may decrease to low-rate or disappear as the session progresses. This is related to the observation that food is more reinforcing for food-restricted than sated subjects (see e.g., Epstein et al., 2003, Phys & Beh). Moreover, consumption of a preferred substance under sated conditions is sometimes subject to postingestive alliesthesia, a phenomenon in which previously appetitive stimuli become aversive (see e.g., Cabanac & Lafrance, 1990, Phys & Beh). The proposed studies require that stable rates of behavior be measured for up to 140 min and that the reinforcer continues to maintain behavior for several days, a goal that appears difficult to obtain in subjects receiving ad l b food and water. Depending on the particular study, either food or water will be used as the reinforcer, and no animal will have simultaneous restricted access to both food and water.	"Water restriction" reflects to availability of water being limited to 30 min per day, provided in average 1 h after completion of the daily training sessions (or an equivalent time during rest periods). The gradual restriction schedule starts with removal of water bottles overnight (Day 1), and then water access limited to 2 h (Day 2), 90 min (Day 3), 60 min (Day 4), 45 min (Day 5), and 30 min (Day 6 and all subsequent days). "Food restriction" refers to a gradual decrease in food provided to maintain body weight at approx. 85% of free-feeding weight. Food consumption will be assessed for each cage by subtracting the weight of food remaining from food provided after a 24h period. A gradual 3% decrease in this amount will be imposed on a daily basis, adjusting up or down by 1% depending on the animals' weight change. Once all animals have reached approx. 85% of free-feeding weight, no further reductions in food amounts	Daily checks will include a visual assessment of animal condition (condition of fur and teeth, injuries, bite marks) and bedding (wet and soiled spots are expected). When treatment is provided through drinking water, food/water consumed will be measured on a daily basis to ensure treatment effectiveness and proper nutrition/hydration. Weight checks will be conducted on a daily basis. Signs of stress (e.g., porphyrin secretions around eyes and nose) will be addressed as appropriate (rehousing, providing extra feeding or extra fluids) and, if not relieved by these methods, BRSF personnel and the project veterinarian will be consulted.	If an animal exhibits at least one sign of dehydration distress (porphyrin secretions, distress when water bottles are removed, excessive hair loss, lethargy, lack of appetite, loss of skin turgor), it will immediately be separated from its cagemate and given ad l b access to water for 24h, checking for wet spots on bedding twice in the 24h period, and for increased activity and general improvements in body condition at the 24h mark. The distressed animal will be separated from its cagemate(s) during water availability for the remainder of the study. If the animal condition is stable but does not improve within 24h, veterinary assessment will be requested to determine whether supplemental fluids should be administered subcutaneously or intraperitoneally. If animal condition continues to remain poor under ad lib water conditions and/or fluid supplementation, the animal will be considered as having reached a humane endpoint and will be euthanized. Food restriction potentially provides a greater problem in group housing conditions because the time of food availability is not controlled by the experimenter but by the speed with which the animals consume the food. We will feed animals their scheduled food amount, and careful weighing will provide a measure of their food intake. Appropriate weight gain will be assessed against growth curves provided by the vendor for a bino rats. If one of the two animals housed in any given cage exhibits inappropriate weight gain (less than 1 gram of gain/day in juveniles under 14 weeks of age, less than 0.5 grams of gain/day in adults over 14 weeks of age and up to 300 g), the animals will be separated at feeding time, with the leaner animal receiving larger-than-scheduled

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				amounts of chow (at least 5 g extra) until it reaches the expected weight (this usually takes 2-3 days). If appropriate weight gain is not observed after 3 days, the leaner animal will be isolated and placed on an ad lib food schedule for 2-3 days. If the animal continues to fail to thrive, veterinary assessment will be requested
17061	Food and Fluid Restriction - Food and Fluid Restriction - Behavior maintained by the use of a preferred food or fluid reinforcer tends to be high-rate during the initial few minutes of a session, and may decrease to low-rate or disappear as the session progresses. This is related to the observation that food is more reinforcing for food-restricted than sated subjects (see e.g., Epstein et al., 2003, Phys & Beh). Moreover, consumption of a preferred substance under sated conditions is sometimes subject to postingestive alliesthesia, a phenomenon in which previously appetitive stimuli become aversive (see e.g., Cabanac & Lafrance, 1990, Phys & Beh). The proposed studies require that stable rates of behavior be measured for up to 140 min and that the reinforcer continues to maintain behavior for several days, a goal that appears difficult to obtain in subjects receiving ad l b food and water. Depending on the particular study, either food or water will be used as the reinforcer, and no animal will have simultaneous restricted access to both food and water.	The restriction schedule will be introduced gradually over the week preceding initiation of the study. "*Water restriction*" reflects to availability of water being limited to 30 min per day, provided in average 1 h after completion of the daily training sessions (or an equivalent time during rest periods). The gradual restriction schedule starts with removal of water bottles overnight (Day 1), and then water access limited to 2 h (Day 2), 90 min (Day 3), 60 min (Day 4), 45 min (Day 5), and 30 min (Day 6 and all subsequent days). "*Food restriction*" refers to a gradual decrease in food provided to maintain body weight at approx. 85% of free-feeding weight. Food consumption will be assessed for each cage by subtracting the weight of food remaining from food provided after a 24h period. A gradual 3% decrease in this amount will be imposed on a daily basis, adjusting up or down by 1% depending on the animals' weight change. Once all animals have reached approx. 85% of free-feeding weight, no further reductions in food amounts will be imposed.	Daily communication with the BRSF personnel as well as clearly labeled cages will ensure that BRSF personnel know that protocol personnel is taking care of feeding and watering animals. A feeding/watering log will be prominently displayed in the housing room, including information of time, amount of food/water administered (or whether ad lib), and initials of experimenter providing the food/water (see attached log). Daily checks will include a visual assessment of animal condition (condition of fur and teeth, injuries, bite marks) and bedding (wet and soiled spots are expected). When treatment is provided through drinking water, food/water consumed will be measured on a daily basis to ensure treatment effectiveness and proper nutrition/hydration. Weight checks will be conducted on a daily basis. Signs of stress (e.g., porphyrin secretions around eyes and nose) will be addressed as appropriate (rehousing, providing extra feeding or extra fluids) and, if not relieved by these methods, BRSF personnel and the project veterinarian will be consulted.	When treatment is provided through drinking water, food/water consumed will be measured on a daily basis to ensure treatment effectiveness and proper nutrition/hydration. Weight checks will be conducted as detailed. Signs of stress (e.g., porphyrin secretions around eyes and nose) will be addressed as appropriate (rehousing, providing extra feeding or extra fluids) and, if not relieved by these methods, BRSF personnel and the project veterinarian will be consulted.
16064-R1	Food Restriction - If a rat eats in the home cage prior to being put into an operant chamber, then the rat is much less l kely to explore the operant chamber and to learn the lever-press response since the lever-pressing behavior is rewarded with food pellets.	the maximum duration of food restriction is approximately 7 days. Most rats will acquire the lever-press response within 3-4 days and the rats may show only a transient loss in body weight.	During the period of food restriction, the rats will be monitored (e.g., observed and weighed) daily to ensure good health and daily weight gain. This daily monitoring is more frequent than the weekly monitoring indicated in The Guide (2011, p. 31).	During this training period (4-7 days), the rats will receive normal chow but the quantity will be restricted to approximately 12-15 g/rat/day. The recommended food rations for rats are 5 g/100 g body weight (The Biology and Medicine of Rabbits and Rodents, 1995) or approximately 15 g for an average adult rat of 300 g (Nutrient Requirements of Laboratory Animals, 1995).