Program Description
Animal Care and Use Program

Veterinary Medical Unit

Jesse Brown VA Medical Center (JBVAMC)
(VA-107)

820 S. Damen Ave
Chicago, Illinois 60612

July 24, 2020

For
AAALAC International

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Appendices

Program Description

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

Section 1. Introduction

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

The program name is the Animal Care and Use Program (ACUP) for the Jesse Brown VA Medical Center (JBVAMC). There is one animal facility referred to as the Veterinary Medical Unit (VMU) covered by this program. Researchers associated with this program maintain appointments at the JBVAMC and either the University of Illinois at Chicago (UIC) or Northwestern University (NU).

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.

Research is an integral and well-supported function of the VA. The JBVAMC provides medical care to eligible veterans in the metropolitan Chicago area and, consistent with the VA mission, supports research in both basic and clinical sciences. The primary goal of all investigations is to improve the quality of health care delivered to our nation's veterans and citizens.

As is mandated by VA Headquarters policy, Research Service directs the animal care and use program, including the centralized facility, the Veterinary Medical Unit (VMU). The VMU is an integral support service for all of the basic biomedical research programs at JBVAMC. The VMU is responsible for ensuring that all animals used in JBVAMC research programs are maintained in accordance with federal and institutional regulations and comply with all existing standards for animal housing and health.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the

United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

At this time the JBVAMC ACUP only supports research involving mice and rats. In that context, the institution and IACUC developed the program as well as policies and guidelines based upon the following regulations, guidelines and standards: 1) the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), 2) the Guide for the Care and Use of Laboratory Animals, 8th edition (Guide) and 3) VHA Handbook 1200.7.

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 Institutional Official (IO) for the JBVAMC is (b) (6) Hospital Director. The JBVAMC Chief of Staff, (b) (6) reports to the Director. The Associate Chief of Staff for Research and Development (ACOS, R&D), (b) (6), reports to the Director via the Chief of Staff. (b) (6) Attending Veterinarian, reports directly to the ACOS for R&D. The JBVAMC Institutional Animal Care and Use Committee (IACUC) is a subcommittee under the R&D Committee serving the Research Service and reports directly to the IO (Director). In accordance with the JBVAMC Letter of Assurance with OLAW, both the attending veterinarian and the IACUC Chair also have direct reporting lines to the IO.

There is a full-time Facility Manager/IACUC Administrator, (b) (6) CMRT (Certified Medical Radiation Technologist) and two full-time animal care technicians. The animal care staff report to (b) (6) and she reports to, (b) (6) the Administrative Officer (AO) for R&D, who reports to the ACOS. (b) (6) also reports to the Attending Veterinarian, (b) (6) DVM.

Additional veterinary support and oversight is provided by (b) (6), Clinical Veterinarian at UIC or another UIC staff Clinical Veterinarian. These individuals are a designee of the Attending Veterinarian ((b) (6)) and report directly to (b) (6).

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.

(b) (6) Hospital Director (Institutional Official, IO)

(b) (6) - Chief of Staff

(b) (6) – ACOS R&D

(b) (6) – AO R&D

(b) (6), MD and (b) (6), MD - Co-Chairs, R&D Committee

(b) (6), PhD - Chair, IACUC

(b) (6), PhD - Vice-Chair, IACUC

(b) (6), DVM - Attending Veterinarian, VMU

(b) (6), CMRT - Facility Manager, VMU/ IACUC, Administrator

(b) (6), PhD - Chair, Subcommittee for Research Safety (SRS) which also serves as the Institutional IBC

(b) (6) - R&D Research Safety Coordinator

(b) (6) - JBVAMC Radiation Safety Officer (RSO)

(b) (6) - JBVAMC Industrial Hygienist (Engineering Services)

(b) (6) - JBVAMC Safety Officer (Engineering Services)

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

As of July 2020, there are 16 principle investigators (PIs) with animals (mice or rats) housed at the JBVAMC VMU that are covered by 32 protocols. The major types of research conducted at the JBVAMC focus on 1) gastrointestinal physiology or pathophysiology (ion and bile acid transport, inflammatory bowel disease and nutrient/cholesterol transport), 2) neurology (etiology and treatment of Parkinson's disease, alcohol abuse, TBI and Alzheimer's), 3) anesthesiology (consequences of overdose and resuscitation), 4) endocrinology (insulin signaling and hormonal regulation of metabolic function and liver disease), 5) rheumatology (pathogenesis and treatment of osteoarthritis). 6) Hematology (mechanisms of blot clot formation). There are no testing or teaching programs at this time.

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

Source of Funding for research conducted at JBVAMC is NIH, VA Merit, UIC or NU institutional funds and private foundations.

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.

All units are included in this program description.

I. 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.

JBVAMC is closely affiliated with UIC and NU. Investigators either conduct VA-funded animal research on-site at the JBVAMC VMU or they utilize animal care resources at their respective affiliate institutions, where they hold academic appointments (UIC, NU). The UIC and NU animal care and use programs are separately AAALAC-accredited. JBVAMC has a formal contract with UIC animal care facility (Biological Resource Laboratory, BRL) to provide veterinary care at JBVAMC VMU, as well as housing VA owned animals at the UIC BRL. JBVAMC also has IACUC Policy Agreements with each affiliate for housing VA owned animals under protocols where specific facilities are required that are not available in the JBVAMC VMU or associated laboratories. These

agreements also contain information regarding the interaction of the respective IACUC's and animal care and use programs.

The JBVAMC receives reports based on affiliate semiannual inspections if VA funded protocols are impacted.VA investigators that maintain animals at an affiliate institution with monies administered through the VA are required to have an approved protocol at both the affiliate institution and JBVAMC.

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

No additional information is provided.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

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

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

The attending veterinarian, AO, IACUC Chair, IACUC administrator/facility manager and IACUC Administrator (or by phone if required due to VA mandate) or meet twice a year in person with the IO and Chief of Staff in conjunction with the institution's semi-annual program and facility review to discuss the respective reviews, the corrective action plan, IACUC departures from the Guide, and other aspects of the animal care and use program. Recommendations/concerns that require immediate consideration between semiannual reviews are generated by the IACUC following deliberation at a convened meeting and forwarded by the Chair of the IACUC to the IO.

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

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:
- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

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

(b) (6), DVM, ACLAM Diplomate, Attending Veterinarian

Authority: (b) (6) has delegated program authority and responsibility for the institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide.

Time Contributed: (b) (6) contributes approximately 8-16 hours a month to the program including on-site visits and off-site review of protocols and consultation on various program related topics. 100% of this time is contributed to the animal care and use program.

(b) (6), DVM, ACLAM Diplomate, Clinical Veterinarian/Attending Veterinarian designee.

Authority: (b) (6) provides primary clinical veterinary support to the program and in (b) (6) absence serves as the attending veterinarian's designee.

Time Contributed: (b) (6) is present at the institution approximately 4-8 hours a month. 100% of this time is contributed to the animal care and use program. In addition, (b) (6) contributes approximately 4 hours a month to the program while off-site providing consultation on various clinical and program related topics.

It should be noted that the UIC veterinary staff, which is composed of five ACLAM Diplomates (including (b) (6) and (b) (6)) and three post-doctoral fellows provides clinical support for emergencies and weekend coverage.

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.

There are none

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 IACUC considers the JBVAMC as having ownership for all animals purchased with funds directly administered through the VA. At this time, all VA investigators have dual appointments at the JBVAMC and an affiliate academic institution (UIC and NU). JBVAMC has IACUC Policy Agreements with each affiliate for housing VA owned animals under protocols where specific facilities are required that are not available in the JBVAMC VMU or associated laboratories. These agreements also contain information regarding the interaction of the respective IACUC's and animal care and use programs.

For a VA grant that has subcontracts or outsourced work involving vertebrate animals to institutions other than UIC and NU, or commercial services, the IACUC considers ownership to reside at the location at which the work is performed. VA investigators that subcontract or outsource work are required to submit a copy of the IACUC approval from the institution at which the subcontracted or outsourced work will be conducted.

Unique to our JBVAMC facility, VA investigators who have an academic affiliation with UIC can house vertebrate animals purchased with monies administered through UIC. In this situation, these mice are considered owned by UIC.

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.

IACUC oversight and evaluation of training program effectiveness

Key to the evaluation of the effectiveness of the institution's training program is feedback the IACUC receives as part of the post-approval monitoring program conducted by the attending veterinarian and his designee, the animal care staff and members of the IACUC. The animal care and veterinary staff continuously evaluate investigator training based on outcome, technical proficiency, and protocol, policy and guideline compliance through daily and weekly assessment of the animals. On a semiannual basis, members of the IACUC including the attending veterinarian inspect all animal facilities, study areas, and laboratories outside the animal facility in which surgery is conducted or animals taken. Findings during the inspection of animal facilities and laboratories play an important role in allowing the IACUC to identify adverse events, assess compliance, and evaluate the institution's training programs.

Training and training documentation

All personnel working with animals (including principal investigators, research technicians, students, and all other personnel) are required to complete on-line training where each individual reviews materials and takes/passes exams every three years on 1) "Working with the VA IACUC", and 2) species-specific training (relevant to our program "Working with Mice (or Rats) in Research Settings"). In addition, members of the VA IACUC are required to complete on-line training "Essentials for IACUC Members". These training modules are administered via CITI programs (Collaborative Institutional Training Initiative; citiprograms.org). The CITI Program sends automatic emails to the individual, prior to the anniversary of their last training date. In addition,

the IACUC Administrator have on-line access to the training records for all individual's affiliated with animal research at JBVAMC. The IACUC Administrator is also responsible for verifying that individuals are current with their training and will also send notices to personnel prior to the anniversary of the previous training date. Only individuals listed on approved protocols, that are current with their on-line training, can conduct animal research.

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

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

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

(b) (6), D.V.M. - Attending Veterinarian and a Diplomate of the American College of Laboratory Animal Medicine (ACLAM). (b) (6) has 32 years of experience in laboratory animal medicine. (b) (6) functions as the Director of the UIC Biologic Resources Laboratory and has programmatic responsibility for the UIC Animal Care and Use Program. In addition, (b) (6) serves as the attending veterinarian for JBVAMC. In this capacity, (b) (6) is a member of the JBVAMC IACUC and has programmatic responsibility for the institution's animal care and use program. (b) (6) has met the C.E. requirements necessary to maintain state licensure and current ACLAM certification.

(b) (6), CMRT - Facility Manager/IACUC Administrator. (b) (6) (b) (6) oversees the day-to-day operation of the JBVAMC VMU. (b) (6) has 26 years of experience in laboratory animal medicine and is a member of the JBVAMC Sub-committee for Research Safety, R&D Medical and Scientific advisory board, JBVAMC R&D Committee (non-voting), and IACUC representative. (b) (6) has attended AALAS, IACUC 101, Essentials of IACUC Administration Overview - PRIM&R, VA symposiums on regulatory compliance, IACUC Administrators Best Practice and SCAW IACUC meetings.

(b) (6) - Clinical Veterinarian and a Diplomate of the American College of Laboratory Animal Medicine. (b) (6) has 22 years of experience in laboratory animal medicine. (b) (6) provides clinical veterinary oversight and support for the JBVAMC animal care and use program and in the absence of (b) (6) serves as the attending veterinarian's designee. (b) (6) has met the C.E. requirements necessary to maintain state licensure and current ACLAM certification.

All the above, every three years, completes a web based training program [Collaborative Institutional Training Initiative (CITI Program); citiprograms.org]

which includes: Working with the VA IACUC, Working with Mice and Rats in a Research Setting and Essentials for IACUC Members.

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

1) Indicate the number of animal care personnel.

Two

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.

(b) (6), Animal Caretaker
Training/experience: Laboratory Animal Technician AALAS certification, 27 years of animal husbandry experience.
Continuing education: Participates as appropriate in (b) (6) Technician Training Program. (b) (6) also completes, every three years, a web-based training program Working with the VA IACUC and Working with Mice and Rats in a Research Setting.

(b) (6), Animal Caretaker
Training/experience: Laboratory Animal Technician AALAS certification, 17 years of animal husbandry experience.
Continuing education: Participates as appropriate in UIC-BRL Technician Training Program. (b) (6) also completes, every three years, a web based training program Working with the VA IACUC and Working with Mice and Rats in a Research Setting.

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.

Prior to approval of any protocol requesting the use of animals the qualifications of the research staff (including principal investigators, research technicians, students, and all other personnel), are assessed by the IACUC and the attending veterinarian. This consists of a review of the personnel qualifications provided within the ACORP. IACUC approval of a proposal can only be granted once the attending veterinarian and the IACUC are satisfied that the personnel are qualified to carry out the procedures listed in the

protocol and/or will obtain training from a qualified individual. A qualified individual may be another investigator with expertise with a specific procedure or the attending veterinarian and/or his designee. In situations where the IACUC asks the attending veterinarian to verify an investigator's proficiency with a technique, the veterinarian will report back to the IACUC the findings.

In addition, all personnel working with animals (including principal investigators, research technicians, students, and all other personnel) are required to complete on-line training where each individual reviews materials and takes/passes exams every three years on 1) Working with the VA IACUC, and 2) species specific training (relevant to our program "Working with Mice (or Rats) in Research Settings"). These training modules are administered via the CITI Program. The IACUC Administrator is responsible for confirming on-line training is current.

Finally, prior to start of animal work, all personnel undergo an orientation on the general practices to follow when working in the VMU.

a) Briefly describe the content of any required training.

1) The web-based CITI program covers many diverse topics including: 1) "Working with the VA IACUC", which has specific modules on USDA pain and distress categories, the use of alternatives, endpoint criteria, and reporting misuse, mistreatment or noncompliance; 2) "Working with Mice (or Rats) in Research Settings", which has specific modules on occupational health issues, injection and blood collection techniques, surgery, supportive care and monitoring, and euthanasia. Prior to initiation of a research project all investigators that work with laboratory animals are required to complete the appropriate CITI Program web-based training and pass the examinations for the respective training modules and thereafter at three-year intervals.

2) All personnel requesting access to the JBVAMC VMU undergo an initial orientation to the VMU facility, which is given by either the VMU Facility Manager and/or designee. During this orientation, personnel are walked through the facility and are trained on the standard procedures used in the VMU which include: PPE requirements, census and surgical record keeping, traffic patterns to maintain clean areas, clean cage preparation, dirty cage disposal, use of procedure and necropsy rooms, etc.). At this time, they are also given a brochure providing information on allergens and zoonotic diseases.

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

Before commencement of work, there are multiple steps that must be completed by research personnel prior to ordering animals, initiating work and/or gaining VMU access. For new investigators, the steps include: 1) approval of the ACORP and Safety Protocol, 2) completion of web-based training modules on working with the VA IACUC and the respective species specific training module, 3) enrollment into the VA occupational health program or an affiliate occupational health program, and 4) orientation with the VMU facility manager and/or designee. Completion of all required components is verified by VMU facility manager/IACUC Administrator, before work can start.

For personnel added to an existing protocol, their qualifications must be reviewed and approved by the veterinarian and IACUC chair, and steps 2-4 completed, before they can work with animals.

c) Describe continuing education opportunities offered.

In addition to on-line CITI Program training and hands-on training by the veterinarian or qualified individuals, JBVAMC investigators are also invited to attend monthly wet labs on handling and biologic sample collection offered through UIC by the veterinary and veterinary technical staff. UIC also sponsors educational seminars, which are available to VA investigators. Topics in the past have included genotyping, common pathologic conditions of rodents, genetic drift, sperm cryopreservation and mouse breeding management.

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

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

The level of training and experience of personnel performing surgery is assessed at the time of the veterinary pre-review and at the time the ACORP and/or a modification is reviewed by the IACUC. If the attending veterinarian or IACUC determine that an investigator's level of training or experience is insufficient as it relates to a surgical technique, then the IACUC will require the investigator to undergo training by the attending veterinarian or designee and/ or possibly another investigator with experience with the technique. In some instances, the IACUC may request that the attending veterinarian or designee observe an investigator perform a technique to verify proficiency.

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

The level of training and experience of personnel performing anesthesia is assessed at the time of the veterinary pre-review and at the time the ACORP and/or a modification is reviewed by the IACUC. If the attending veterinarian or IACUC determine that an investigator's level of training or experience is insufficient as it relates to performing anesthesia, then the IACUC will require the investigator to undergo training by the attending veterinarian or designee and/ or possibly another investigator with experience with the anesthetic protocol. In some instances, the IACUC may request that the attending veterinarian or designee observe an investigator perform anesthesia to verify proficiency.

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

The level of training and experience of personnel performing euthanasia is assessed at the time of the veterinary pre-review and at the time the ACORP and/or a modification is reviewed by the IACUC. If the attending veterinarian or IACUC determine that an investigator's level of training or experience is insufficient as it relates to the proposed euthanasia technique, then the IACUC will require the investigator to undergo training by the attending veterinarian or designee.

The VMU has two central CO2 euthanasia stations and a CO2 euthanasia station in the BSL-2 room. Each station has a cervical dislocator and posted SOP. The SOP details CO2 flow rates and the cervical dislocation procedure that is used immediately following CO2 exposure as a secondary method of euthanasia.

The VMU staff is often asked by veterinary or research staff to euthanatize animals. All VMU technicians are experienced animal technicians and havereceived in-house instruction on the performance of euthanasia using CO2, followed by cervical dislocation, to ensure death.

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).

There are six institutional entities at JBVAMC, which interact at various levels to ensure the health and safety of all individuals working with animals.

1) JBVAMC Employee Health Services, which operates the Occupational Health and Safety Program (OHSP) for all paid VA employees (facility/staff), including personnel involved in animal care and/or use, as mandated by VA policy (VHA Handbook 1200.7, 10 c.). All paid VA employees working with animals at JBVAMC are in the VA OHSP. Those individuals involved in animal research at the JBVAMC employed by or are students of affiliate institutions (UIC or NU), are enrolled in their respective OHSP program.

2) JBVAMC Subcommittee for Research Safety (SRS; which includes review of protocols using recombinant DNA and infectious agents [IBC]) is a committee that reviews and approves personnel and environmental safety aspects of all research conducted at JBVAMC and all VA funded research conducted at affiliates (UIC and NU). The SRS meets monthly to evaluate and monitor general workplace safety, as well any work related to biological hazards, human or non-human cells or tissues samples (including bodily fluids, cultures, cells or cell lines), recombinant DNA, chemicals, controlled substances, ionizing radiation, and non-ionizing radiation (lasers, UV, radiofrequency or microwave sources). All VA funded investigators (including those working with animals) are required to submit a full Research Protocol Safety Survey every 3 years (requiring annual approval). Any changes made to the approved safety protocol mustbe submitted as modifications for review and approval. The IACUC committee communicates to the SRS any safety concerns. For those VA funded animal protocols conducted at the affiliates (UIC and NU), SRS requires confirmation of the respective institutional safety approval. In addition, JBVAMC VMU also houses animals under non-VA funded protocols administered through UIC, and the JBVAMC IACUC requires confirmation of safety/IBC approval from UIC for these studies.

3) Use and approval for radioactive material sources of ionizing radiation is the responsibility of the JBVAMC Radiation Safety Committee (RSC) and is executed and administered by the JBVAMC Radiation Safety Officer (RSO). The Committee reports to the IO through the Chief of Staff and to the Environment of Care Committee (see below). Use of radioactive

materials (including those used in animal research) requires approval by the RSC of a Radiation Safety Application and this approval is forwarded to the SRS. Work with radioactive material in animals cannot begin until the investigator receives approval from both the SRS and RSC.

4) JBVAMC Engineering Services has an Industrial Hygienist, that oversees biological and chemical hazards and a Safety Officer that oversees fire safety and ergonomics for the whole medical center. These individuals are available for consultation with the research staff and SRS to assess potential risks, develop procedures, evaluate exposures, and develop appropriate remediation plans.

5) JBVAMC Environment of Care Committee – consists of individuals with specific expertise in patient care, health and safety, which include, but is not limited to the R&D Research Safety Coordinator, Industrial Hygienist, Safety Officer, Research Pharmacist and the Radiation Safety Officer (RSO). This committee inspects each area of JBVAMC (including R&D laboratories and VMU) twice a year for compliance in all aspects of patient, personnel, environmental and laboratory safety and reports their findings directly to the IO. The report is also transmitted to the SRS, where deficiencies are communicated to the appropriate personnel for remediation.

6. JBVAMC Research Compliance Officer- Reports to the IO and reviews 5% of the IACUC and Safety protocols twice a year for compliance. (b) (6) also provides an annual report to the IO regarding all compliance issues associated with IACUC and Safety Protocols.

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.].

As part of their day-to-day function, the veterinary and animal care staff continuously assesses the animal facility for the presence of intrinsic hazards and evaluates the ongoing use of hazards in the workplace. As intrinsic hazards or problems with ongoing hazard work are identified, the appropriate entities listed above are consulted and/or changes in work practices and training are initiated.

The Environment of Care Committee inspects each area of JBVAMC (including R&D laboratories and VMU) twice a year for compliance in all aspects of patient, personnel, environmental and laboratory safety and reports their findings directly to the IO. The report is also transmitted to the SRS, where deficiencies are communicated to the appropriate personnel for remediation.

The R&D Research Safety Coordinator conducts quarterly inspections for work related to hazards in all JBVAMC laboratories, including the VMU. Reports are sent to the responsible individuals (PI's, lab managers or supervisors) for immediate remediation. The reports and corrective actions are also discussed at the following SRS committee meeting.

The VA ACORP contains a protocol specific biosafety section (Section P) that requires the investigator to indicate whether they will be administering substances other than those used routinely for husbandry or veterinary care. If the investigator checks "yes" to this section then the investigator is required to complete the biosafety appendix (Appendix 3), which requires categorization of agents administered in terms of potential type of hazard and a description of the provisions in place to reduce exposure and to assure appropriate training. If the investigator identifies agents as toxic, infectious, radioactive or containing recombinant nucleic acid biohazards, then the relevant committees (SRS, Radiation Safety Committee) and the R&D Research Safety Coordinator, must evaluate the methods used in working with the hazard and contact the attending veterinarian/IACUC to discuss any additional precautions, whereupon these changes will be incorporated into the IACUC protocol prior to approval. Section Z of the ACORP has a hazard certification section for the investigator. The IACUC Chair, attending veterinarian and safety officials sign the ACORP indicating appropriate precautions are in place and that the appropriate committee has approved work with the hazardous agent. Thus, hazard identification, evaluation and control are done on an individual protocol basis.

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

As part of the semiannual program and facility review, the facility is assessed for the presence of intrinsic hazards and the ongoing use of hazards in the workplace is evaluated. The identification of intrinsic hazards and/or deficiencies in the use of hazards is brought to the attention of the full IACUC at a convened meeting as part of the corrective action plan to address program and facility deficiencies. The IACUC notifies the R&D and IO about the corrective action to take, and a timeline for completion.

In addition, the R&D Safety Coordinator inspects quarterly all laboratories including the VMU. The SRS is notified of any deficiencies and may recommend a plan of action to correct the deficiencies.

The Environment of Care (EOC) Committee inspects all areas of the medical facility, including research laboratories and VMU twice a year for intrinsic hazards and reports their finding to the IO and SRS, where the SRS will formulate and oversee a remediation plan.

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]

It is the responsibility of the R&D staff to report an exposure/accident/illness immediately to their supervisor, who in turn reports it to the R&D AO, who does the fact-finding of the incident and completes, validates and signs an on-line accident report, within 48h. Reporting safety related workplace incidents (such as suspected exposure to biohazards/chemicals, bites/scratches, falls, etc.) is conducted through the VA JBVAMC on-line ASISTS program.

ii. Standard Working Conditions and Baseline Precautions

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

1) Medical Evaluation and Preventive Medicine for Personnel [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

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

All individuals working at the JBVAMC (including those working with animals) are enrolled in JBVAMC's OHSP or the equivalent at the respective affiliate institution (UIC or NU).

b) Describe provisions for allowing an individual (following completion of individual health and job-related risk assessments) to decline

participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
Note: Do not include names of the personnel

There is no mechanism to allow an individual to decline participation in an occupational health program. All individuals requesting access to the VMU are required to enroll or be enrolled in either the JBVAMC OHSP or an equivalent affiliate institution's OHSP.

0% or personnel have declined participation in the medical evaluation program.

c) Describe provisions for assuring confidentiality of medical information.

All medical information on personnel is maintained by VA EHS or the respective affiliate institution's employee health center.

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

Engineering staff and outside contractors enter the VMU on an as needed basis. These individuals do not have direct contact with animals. An orientation regarding proper PPE use and VMU general conduct is given prior to working in the VMU and all individuals are escorted by VMU staff.

Personnel working in open laboratories (who do not have direct contact with animals) are informed by the Principle Investigator regarding specific issues related to their studies.

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.

JBVAMC, Employee Health Services, operates the Occupational Health and Safety Program (OHSP) for all paid JBVAMC employees (facility/staff), including personnel involved in animal care and/or use. Prior to working with animals, individual's fill out a research specific form (JBVAMC R&D Admin/IACUC VMU Annual Questionnaire), which indicates the hazards they may be exposed to (including working with animals) while conducting their research at JBVAMC and any relevant health information which may impact their ability to work with animals. The individual fills the form out and places it in a sealed envelope which is given to EHS. The EHS staff will address any health concerns of the employee and determines if special precautions are required for an individual to safely work with animals or perform specific duties. EHS also offers routine vaccinations, including Tetanus.

All other individuals not directly paid by the VA, but working on VA funded protocols, are enrolled in OHSP of their respective affiliate institution (UIC or NU).

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.

The JBVAMC EHS staff (after hours the VA Emergency Room Staff) are available if an individual is injured while working (such as animal bites, allergic reactions, slips, falls, potential hazard exposure, etc.), to provide immediate treatment and hospitalization, if necessary. Immediate/Emergency care is given regardless of institutional OHSP affiliation. Any follow-up care will be addressed at the OHSP in which the individual is enrolled.

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.

All personnel obtaining access to the JBVAMC VMU must be enrolled in either the VA's or an affiliate institution's OHSP. In addition, all personnel must undergo an initial orientation to the VMU facility, which is given by either the VMU Facility Manager and/or designee. During this orientation, personnel receive training on the standard procedures used in the VMU which include; proper use of PPE, location of eyewash stations and safety (chemical) showers and availability of standard shower facilities. During the initial orientation, individuals are given a brochure (Occupational Health Program for Individuals with Animal Contact) providing information on seeking treatment and reporting accidents/illness. This brochure also includes information on allergens, zoonotic diseases and how to handle a bite or scratch wound. In addition to this face-to-face training, all staff working with animals take on-line training through the CITI Program, where the modules "Working with Mice" and "Working with Rats" also cover risks related to allergens and zoonotic diseases.

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.

VMU Staff: Clean scrub suits/uniforms/lab coats are provided to all VMU employees daily. Rubber, steel-toed, skid-resistant boots or shoes, lumbar and wrist supports, and eye and ear protection are also provided.

Research and VMU Staff: The following standard PPE is provided for research and VMU staff: surgical head covers, masks, gowns, shoe covers and nitrile gloves.

b) Describe arrangements for laundering work clothing.

The VMU has 2 washers and dryers and provides "in house" laundry service for staff uniforms.

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.

Locker rooms with showers and sinks are provided for employees and research staff in rooms (b) (6) and (b) (6). Sinks, available to both VMU and research staff, are present in some animal and support/procedure rooms within the facility. VMU and Research staff wear a full complement of PPE in animal rooms, which is removed prior to leaving the facility. VMU staff uniforms worn in animal areas can only be worn outside the VMU if covered with a laboratory coat.

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

VMU policy does not allow eating, drinking, smoking, cosmetic application, contact lens manipulation or hair care in any animal room or laboratory area. A lunch/break room (b) (6) and offices are available for breaks for animal care and investigative staff. The JBVAMC is a smoke-free environment.

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).

Signs are posted in the cage wash area, indicating ear protection is required. A HEPA filtered dumping station is used to discard bedding in biohazard bags. Chemicals used for sanitizing rooms and the cage washer are pre-mixed in a closed system, which eliminates the exposure of the VMU staff to concentrated chemicals. Chemical drums in use are on rollers and reserve chemical drums are stored on a spill pallet. A Tommy lift is available for moving pallets of bedding and feed. Two chemical fume hoods are available, to be used when working with volatile chemical hazards. A biosafety cabinet is available for working with biohazards. The VMU also has four animal changing stations.

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

All animal species (mice and rats) housed at the JBVAMC's VMU have the potential to cause allergic reactions in sensitized personnel. General precautions against allergen exposure include the use of PPE in all animal

rooms, dedicated work clothing for staff and access to shower facilities. Additional strategies used to minimize allergen exposure include the use of static microisolator cages and laminar flow workstations for cage changing and when possible manipulating animals.

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

For general precautions against zoonoses, PPE is available in all animal facilities, shower facilities are available, and dedicated work clothing or scrubs are provided to animal facility staff.

At this time, only SPF mice and rats are purchased and used in the VMU. Animals are maintained in sterile static microisolator cages and are changed in animal transfer stations with HEPA filters. Therefore, the risk of zoonotic disease transfer is considered minimal.

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

Biosafety cabinets, animal transfer stations, fume hoods, medical waste dump stations are certified semi-annually. Chemical showers are checked and flushed monthly and Eye wash stations are checked and flushed weekly.

e) Respiratory Protection

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

Routine Cage Changing- There is a negative dump station on the dirty side of the cage washroom and four portable animal changing stations. In addition, face masks are required PPE for cage changing.

Working with Volatile Chemicals- Fume hoods are present in the VMU to support work with volatile chemicals.

Working with BSL-2 Agents- a biosafety cabinet is located in the designated BSL-2 room. All work involving BSL-2 agents require an N-95 mask or PAPR.

Depending on the agents and recommendation from the IACUC, SRS and EHS, additional respiratory protective equipment, such as chemical cartridges, would be provided.

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

Should a researcher's or VMU staff member's health condition and/ or research project require a respirator, they would receive a health clearance from EHS and fit testing performed on an annual basis (independent of VA or Affiliate OHSP enrollment).

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

The specific respiratory equipment is selected based on the level of hazard assessed by the IACUC, SRS and EHS. The fume hoods, biosafety cabinet, dump station, and animal changing stations are inspected and certified semi-annually. For those situations requiring respirators, fit testing is performed annually.

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).

One walk-in rack washer with interlocked doors
One bottle washer
One medium size bulk autoclave

All equipment listed above has signage directing users to emergency shut-off buttons on the equipment and emergency power shut-off switches in the room. In addition, the rack washer has signage directing users on the use of emergency pull-cords within the machine.

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

additional Appendix.

Not applicable

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

VA motorized, temperature controlled, vehicles can be used to transport mice and rats between the JBVAMC and UIC or NU. Only non-infectious animals are transported in the vehicle. The animals are transported in secured microisolator cages, which are placed within a secondary container. The outside of the cages is disinfected prior to transportation.

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

When used in laboratories, volatile anesthetics must be administered within a certified fume hood or have scavenging devices (charcoal filters) connected to the anesthetic machine. The VMU surgery rooms are equipped with in-house medical gas evacuation and the VMU has two procedural rooms with fume hoods.

The JBVAMC has programs in place for the annual certification of vaporizers, anesthetic machines, and fume hoods.

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.

Agent	Hazard Level	Species
Adeno Associated virus	BSL-1	Mice
Adenovirus, attenuated	BSL-2	Mice
Modified E. coli	BSL-2	Mice
Clostridium Difficile (TcdA,TcDb,CDTab, R20291)	BSL-2	Mice
Cryptosporidium Parvum	BSL-2	Mice
Vibrio cholerae toxin	BSL2	Mice
Bilophila Wadsworthia	BSL2	Mice
Heat labile and stable toxins	BSL2	Mice
Shiga Toxin	BSL2	Mice
Accessory cholera enterotoxin	BSL2	Mice
Fusobacter nucleatum	BSL2	Mice
EIEC(strain O29:NM)	BSL2	Mice
Salmonella typhimurium	BSL2	Mice
Human microbiota	BSL2	Mice

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

BrdU - 5-bromo-2'-deoxyuridine
Classification: Toxin, Potential Mutagen, Potential Teratogen

2,4,6-trinitro benzene sulfonic acid (TNBS)
Classification: Explosive in concentrated powder form.

Pertussis Toxin
Classification: Irritant

1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)
Classification: neurotoxin

Tamoxifen
Classification: potential carcinogen and teratogen

Azoxymethane (AOM)
Classification: toxin, irritant, carcinogen

Pazopanib
Classification: Irritant, hepatotoxic

Paraformaldehyde:
Classification: Irritant

Freund's Adjuvant
Classification: Irritant

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

A shielded rodent NMR is maintained in the VMU.

IVIS Imaging System – X-Rays

H3 and C14 labeled lysophosphatidylcholine-DHA

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

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

The VA ACORP contains a biosafety section (Section P) that requires the investigator to indicate whether they will be administering substances other than those used routinely for husbandry or veterinary care. If the investigator checks "yes" to this section then the investigator is required to complete the biosafety appendix (Appendix 3), which requires categorization of agents administered in terms of potential type of hazard and a description of the provisions in place to reduce exposure and to assure appropriate training. If

the investigator identifies agents as toxic, infectious, radioactive or containing recombinant nucleic acid biohazards, then the relevant committees (SRS, Radiation Safety Committee), and the R&D Research Safety Coordinator, must evaluate the methods used in working with the hazard and contact the attending veterinarian/IACUC to discuss any additional precautions, whereupon these changes will be incorporated into the IACUC protocol prior to approval. Section Z of the ACORP has a hazard certification section for the investigator. The IACUC Chair, attending veterinarian and safety officials sign the ACORP indicating appropriate precautions are in place and that the appropriate committee has approved work with the hazardous agent. Thus, hazard identification, evaluation and control are done on an individual protocol basis.

The VA policies and procedures for governing experimentation with hazardous agents and the entities that are mandated by the VHA Handbook 1200.8 to oversee work with hazardous agents are briefly summarized as follows:

1) The R&D Subcommittee for Safety (SRS) reviews and approves all safety aspects of research conducted at JBVAMC including work with chemicals, biological, radioisotopes and recombinant DNA. Policies and procedures used by the SRS include NIH Guidelines for Research Involving Recombinant DNA Molecule, the Federal Register on the Possession, Use and Transfer of Select Agents and Agricultural Bioterrorism Protection Act, and the Possession, Use and Transfer of Biological Agents and Toxins. It should be noted that the Industrial Hygienist is a standing member on the SRS Committee. For agents (chemical and biological) the Industrial Hygienist will review the safety protocol for appropriate handling, storage, use and disposal and where deficiencies are noted will work with the investigator to develop an appropriate plan for final approval by the SRS. The Radiation Safety Officer is also a standing member on the SRS committee, which will review specific aspects of use of ionizing radiation (see below).
2) Radiation Safety protocols, governing all use of ionizing radiation (including protocols involving animals) are reviewed and approved by the JBVAMC Radiation Safety Committee. This committee reviews and approves the procurement, use, storage, and disposal of all sources of ionizing radiation to ensure compliance with the Nuclear Regulatory Commission that grants authority to the National Health Physics Program for oversight of VA program. The Radiation Safety Officer is a standing member on both the Radiation Safety Committee and the SRS Committee, and serves an expert interface between these two committees to ensure safe use and compliance of ionizing radiation in a research setting.

3) The R&D Research Safety Coordinator is responsible for day-to-day oversight and control. The R&D Research Safety Coordinator is a member of the SRS Committee and the IACUC Committee allowing for transparent and timely communication regarding any safety issues related to animal research.

In addition to specific policies on the use of hazardous agents contained within the VHA Handbook, the following manuals are used by the above entities to ensure compliance: the JBVAMC Chemical Hygiene Plan (provided to all PIs and located in their laboratories) and the JBVAMC Radiation Safety Manual (provided to investigators working with radioactive materials). These manuals and supporting policies will be available at the time of the site visit.

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.

As part of their day-to-day function, the veterinary and animal care staff continuously assesses the animal facility for the presence of intrinsic hazards and evaluates the ongoing use of hazards in the workplace. As intrinsic hazards or problems with ongoing hazard work are identified, the appropriate entities listed above are consulted and/or changes in work practices and training are initiated. As part of the semiannual program and facility review, the facility is assessed for the presence of intrinsic hazards and the ongoing use of hazards in the workplace is evaluated. The identification of intrinsic hazards and/or deficiencies in the use of hazards is brought to the attention of the full IACUC at a convened meeting as part of the corrective action plan to address program and facility deficiencies. The IACUC notifies the R&D and IO about the corrective action to take, and a timeline for completion.

In addition, the R&D Research Safety Coordinator inspects quarterly all laboratories including the VMU. The SRS is notified of any deficiencies and may recommend a plan of action to correct the deficiencies.

Finally, the Environment of Care Committee inspects all areas of the medical facility, including research laboratories and VMU twice a year for intrinsic hazards and reports their finding to the IO and SRS, where the SRS will formulate and oversee a remediation plan.

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.

Animal husbandry is handled by the PI's laboratory staff for any experiment involving exposure of animals to hazardous agents. General SOP's have been developed for handling animals and waste exposed to BSL-2 agents and hazardous chemicals. Animals exposed to BSL-2 agents and those chemical agents considered high risk (after IACUC and SRS review) are housed in microisolator cages with disposable bottoms. Any additional precautions/procedures that are agent dependent are outlined in the ACORP.

Hazardous wastes (infectious, toxic, radioactive) – When the need arises, the disposal of the hazardous waste is coordinated with the appropriate JBVAMC Safety Officers.

1) Animals and/or bedding contaminated with BSL-2 agents: Wire lids, filter tops and water bottles are sprayed with MB-10 and are bagged and autoclaved prior to washing. Disposable cage bottoms and bedding are bagged and placed in a red biohazard bin and removed by a company licensed for the disposal of medical waste.
2) Animals and/or bedding contaminated with chemicals: Wire lids, filter tops and water bottles are sprayed with the appropriate deactivating agent and are washed. Disposable cage bottoms and bedding are bagged and placed in a red biohazard bin and removed by a company licensed for the disposal of medical waste.
3) Animals and/or bedding contaminated with radionuclides is disposed of under the auspices of the JBVAMC RSO and in a manner consistent with the National Health Physics Program.

Sharps are placed in identified sharps containers. Containers are removed by Environmental Management Services for delivery to a company licensed for the disposal of medical waste.

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

JBVAMC, Employee Health Services, operates the Occupational Health and Safety Program (OHSP) for all paid JBVAMC employees (facility/staff), including personnel involved in animal care and/or use involving experimental hazards. Prior to working with animals, individual's fill out a research specific form (JBVAMC R&D Admin/IACUC VMU Questionnaire), which indicates the "experimental hazards" they may be exposed to. The individual fills the form out and places it in a sealed envelope which is given to EHS. The EHS staff will address any health concerns of the employee and determines if special precautions or monitoring are required for an individual to safely work with hazardous agents. At this time, any change of health and/or exposure to hazardous materials are discussed and recorded

and appropriate steps are taken to ensure the health and safety of the employee.

All other individuals not directly paid by the VA, but working on VA funded protocols, are enrolled in OHSP of their respective affiliate institution (UIC or NU).

The JBVAMC EHS staff (after hours the VA Emergency Room Staff) are available if an individual is injured while working (such as animal bites, allergic reactions, slips, falls, potential hazard exposure, etc.), to provide immediate treatment and hospitalization, if necessary. Immediate/Emergency care is given regardless of institutional OHSP affiliation. Any follow-up care will be addressed at the OHSP in which the individual is enrolled.

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.

Details of the hazard and standard operating procedure, to be used in animal studies, are provided in the ACORP, in addition to the qualifications and level of training of staff which will perform the work. This information is reviewed by both the VA IACUC, SRS, and if appropriate the Radiation Safety Committee. A designee with the appropriate expertise will provide specific hazard room training prior to the work being conducted. These individuals may include, but are not restricted to, other qualified PIs or laboratory staff, veterinarian, Radiation Safety Officer, Industrial Hygienist or R&D Research Safety Officer.

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

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

Room (b) (6) is a limited access room with 120 sq. ft. of space used to support BSL-2 animal research projects. The ventilation to the room is negative to the corridor, and the room contains a sink, Class II biosafety cabinet and a CO2 euthanasia station.

There is one procedure room (b) (6)), which has 323 sq. ft. of space, used to support radioisotope work. The room is equipped with a Geiger counter.

There are two procedure rooms with fume hoods and eye wash stations (Rm. (b) (6), 161 sq. ft. and Rm. (b) (6), 80 sq. ft.) that support the intermittent administration of volatile chemicals.

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.

Based upon risk assessment, a designated animal housing room may be assigned for exclusive work with animals exposed to chemical hazards or animals may be maintained in a standard animal housing room. Regardless of where animals are housed, specific hazard signage is provided at the room and cage level. The PI and their laboratory staff are responsible for husbandry of animals exposed to chemical hazards per the approved SOP's and specific procedures outlined in the ACORP.

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

Class II Biosafety Cabinet and fume hoods are certified semi-annually through engineering services.

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

All routine husbandry is handled by the PI's laboratory staff for any experiment involving exposure of animals to hazardous agents. General SOP's have been developed for handling animals and waste exposed to BSL-2 agents and hazardous chemicals. Any additional precautions/procedures that are agent dependent are outlined in the ACORP.

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.

Animals are not housed or used in patient areas.

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.

Animals are transported outside the VMU to research laboratories in their primary enclosure. In this case, the primary enclosure is covered to prevent visualization of the animal and only non-patient elevators are used to transport animals between floors. Animals exposed to Hazardous Agents are not allowed outside of the VMU.

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.

Per VHA Handbook 1200.7, IACUC members in consultation with the R&D Committee must forward the name(s) of nominees for the IACUC to the Medical Center Director. The Medical Center Director (IO) must officially appoint members in writing for three-year terms with annual review.

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

The Committee meets monthly or more frequently if needed.

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

New IACUC members meet with the IACUC Administrator for an orientation and are provided access to an electronic copy of 1200.7, the assurance letter and PHS policy. In addition, copies of the current Guide are available in the R&D office and VMU.

Voting members meet with the IACUC Chair and/or Attending Veterinarian to discuss review of specific protocol sections.

IACUC members are also required to complete the CITI Program web-based course, "Essentials for IACUC Members".

VA Central Office provides IACUC stations with protocol review scenarios, which are brought to the IACUC meetings periodically.

The Attending Veterinarian, IACUC Administrator and IACUC Chair participate in VA, PRIM&R, and SCAW webinars and meetings.

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.

All protocols (ACORPs) involving the use of animals in research, testing or teaching are submitted through IRBNet to the JBVAMC Research Administration. Each protocol/ACORP is assigned a unique number for tracking and record keeping purposes.

The IACUC Administrator notifies the attending veterinarian that a protocol/ACORP has been submitted for veterinary pre-review. Following the veterinary pre-review, the attending veterinarian submits a list of concerns and/or additional items that need to be addressed in the investigator's protocol package. The Veterinarian pre-review concerns are provided to the investigator on the Veterinary Consultation Review Form. The investigator must revise the ACORP and submit the revised ACORP to IRBNet by the "Revised Submission Due Date", for the application to be reviewed at the next full IACUC meeting.

The IACUC Chair, IACUC Administrator then assigns a primary reviewer to present the revised submission at the next convened IACUC meeting and to match the scientific objectives of the animal care protocol with those of its associated grant proposal, where appropriate. The attending veterinarian and the Chair of the IACUC serve as secondary reviewers. The protocol is also distributed to all

members of the IACUC along with an agenda which outlines reviewer assignments through access in IRBNet. All protocols are reviewed at a convened meeting of a quorum of IACUC members. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the proposal is withheld although the protocol may be discussed, and suggestions communicated to benefit the investigator. No member of the IACUC may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest except to provide information requested by the IACUC. In addition, a member who has a conflicting interest cannot contribute to the constitution of a quorum.

The primary reviewer is responsible for submitting a IACUC Protocol Reviewer Form uploaded to IRBNet, which summarizes the work and lists any clarifications/modifications noted by the primary reviewer and additional concerns discussed at the IACUC meeting and the action of the IACUC committee. This form is used to generate the letter that is forwarded to the investigator.

The IACUC will take one of the following three actions as it relates to the review of an ACORP: approval, request for clarifications/modification to secure approval, or approval withheld. In the case the committee elects to request clarifications/modifications to secure approval, the IACUC may determine by unanimous vote to use Designated Member Review (DMR) to review and approve the requested changes to the protocol after full committee review. At least two IACUC members responsible for DMR are assigned by the IACUC at the time of the protocol review. If approval is withheld from a protocol or a unanimous vote to use DMR is not obtained, the investigator must address the concerns prior to its review at the next convened meeting of the IACUC. The IACUC notifies investigators in writing of the outcome of each respective protocol.

It should be noted that investigators conducting VA funded animal research at affiliate institutions (UIC or NU) and/or conducting research at the JBVAMC VMU using monies for research administered through UIC must obtain appropriate approvals from the respective affiliate IACUC prior to VA approval. The specific order of approval is outlined in the IACUC agreements between the JBVAMC and the respective affiliates.

Finally, in the case in which a VA Merit application has received a fundable score, prior to release of monies, a VA ACORP must be submitted for review and the IACUC conducts a side-by-side "just-in-time" (JIT) comparison of the ACORP and the grant proposal. Moreover, in such cases, the ACORP is forwarded to VA Central Office for a mandatory secondary veterinary review. Depending upon the level of concerns generated during the secondary review, the JBVAMC IACUC may require the investigator to address specific concerns of the Central Office secondary veterinary review prior to the release of funding.

The VA IACUC reviews all protocols in a similar manner regardless of the funding source, including pilot studies and those that are internally funded. This review includes scrutiny of scientific merit. If necessary, a researcher may be asked to clarify scientific reasoning. Alternatively, complex matters may be investigated with literature searches and/or input from individuals with pertinent expertise. Additionally, all research conducted at the VA must be approved by the R&D Committee. The R&D committee reviews proposed research to ensure that work performed at the VA is scientifically sound and is completed in a safe and conscientious manner.

The VA mandated ACORP, includes a section (page 2, item B) that requires investigators to provide a description of the relevance and harm/benefit analysis. More specifically the section requires the investigator to provide a description of how the research project is intended to improve the health of people and/or animals, or otherwise serve the good of society. In addition, the investigator must explain how these benefits outweigh the pain or distress that may be caused in the animals as part of the research project. This section must be completed using non-technical language that a senior high school student could understand.

The ACORP has specific sections that require investigators to justify the animal type and number of animals used per experimental group (page 2, items C.2.b). Moreover, the ACORP specifically states that the number of animals requested should be justified statistically and that a power analysis is strongly encouraged to justify group sizes when appropriate.

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.

Modification requests to existing protocols are submitted to IRBNet. The modification request must be submitted on the JBVAMC IACUC Modification Request Form. Modification requests from investigators using VA funds to conduct research at affiliate institutions or using non-VA funds administered by the affiliates to conduct research at JBVAMC VMU, must also be submitted to and approved by the affiliate institution's IACUC. The affiliate institution's modification forms along with the approval letter must be submitted with the JBVAMC Modification Request Form.

The IACUC Administrator notifies the Chair (or designee) and/or the attending veterinarian of the modification form and any applicable affiliate institution forms, to determine the level of review required for the modification request. Levels of review include: Administrative, Administrative with Veterinary Verification and Consultation and Full Committee Review/Designated Member Review.

Modifications eligible for administrative review and approval include: protocol title changes, the addition of a new strain or stock of animals; a decrease in animal numbers that does not change the scope/intent of the project; the addition of animals less than 10% of the number approved in the original protocol, the addition and deletion of personnel exclusive of the PI; change in location site in which a procedure is performed; and the addition of funding. The Chair and/or Vice-Chair of the IACUC approve all modifications eligible for administrative approval. All administrative approved modification requests are presented to the IACUC as part of the agenda at the next convened meeting of the IACUC.

Modifications eligible for Administrative Review with Veterinary Verification and Consultation and approval include: change from one drug within a classification to another in the same classification; the addition of procedures within the scope (objectives) of the approved protocol that do not increase the invasiveness of the approved protocol and/or the pain category of the animals used; a change from one AVMA acceptable or conditionally acceptable method of euthanasia to another; an increase in the frequency of a procedure; and the change from one appropriate anesthetic/analgesic to another. The Chair and/or Vice-Chair of the IACUC in consultation with the attending veterinarian or designee approve modifications eligible for administrative approval with veterinary consultation. All such modification requests are presented to the IACUC as part of the agenda at the next convened meeting of the IACUC.

Modifications requiring Full Committee/Designated Member Review and approval include: changes in the principal investigator, the addition of animals 10% or greater of the number approved in the original submission, procedures that increase the invasiveness of the approved protocol and/or the pain category of the animals used in the protocol, the addition of a surgical procedure or the upgrade of a terminal surgical procedure to a survival surgical procedure or a multiple survival procedure, a request to withhold analgesics, change in or the addition of an organ system, change in study objectives, the addition of food or fluid restriction beyond overnight fasting, the addition of a procedure causing unalleviated pain and or distress, the addition of an euthanasia method not classified by the AVMA as acceptable or conditionally acceptable by the AVMA, and changes that impact personnel safety. Modifications requiring Full Committee/Designated Member Review are reviewed in their entirety by a quorum of the IACUC at a convened meeting. In special circumstances, as deemed necessary and appropriate by the IACUC Chair or Chair's designee, such modifications may be reviewed using the Designated Member Review process described in the JBVAMC's Letter of Assurance with OLAW.

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

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

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

The ACORP has a specific section that asks PIs to address the issue of endpoint criteria for animals both on and off study (page 10, item T). Thus, experimental endpoints are assessed by the attending veterinarian and the IACUC for all protocols submitted to the JBVAMC IACUC. Moreover, the ACORP requires investigators to categorize animal use in accordance with the USDA Pain and Distress Categories. All animal use proposed as Category E must be scientifically justified in the ACORP.

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

If there is a potential for pain or distress to occur before scientific endpoints can be reached, plans are developed to prevent, terminate, or relieve the pain or distress as early as possible. Measures taken include providing analgesics, employing monitoring forms, and setting monitoring schedules so that the monitoring frequency increases with the potential for pain and distress. When a monitoring form is required, it is included as part of the protocol and reviewed by the IACUC. For protocols with the highest potential for pain or distress, the attending veterinarian and/or designee assists the PI in the development of the monitoring forms and the monitoring schedule. Then monitors the animals to ensure the humane endpoint criteria are met.

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.

Research staff is primarily responsible for monitoring animals for potential pain and distress; however, depending upon the model and the potential for welfare concerns, the veterinary staff may also play a significant role in monitoring the animals.

As part of the protocol review process the IACUC assesses the investigator's experience with the model. Depending on the investigator's experience and/or the proposed model, the IACUC may require the veterinary staff to review endpoint criteria with the investigator and their staff prior to study initiation, observe the animal's side-by-side with the investigator and their staff, or observe animals independent of investigator observations.

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

In the annual protocol renewal form, the PI must certify that experiments are providing usable data and that no unanticipated issues of animal welfare have arisen. If the PI does not provide written agreement with these statements, an explanation must be submitted to the IACUC with the renewal form. Additional means to identify unexpected experimental outcomes include daily health assessment of rodents by animal care staff, self-reporting by research staff, and veterinary observation during weekly clinical rounds in which each animal in the facility is observed. If the experimental outcome is inconsistent with that described in the protocol, the IACUC is notified.

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."

It should be noted that the use of restraint procedures at the JBVAMC have not been used in the last fifteen years.

The VA IACUC defines prolonged restraint as "The use of manual or mechanical means for periods of time greater than 30 minutes to limit some or all of an animal's normal movement for the purpose of experimental manipulation". Tether systems are not considered by the VA IACUC to be prolonged restraint.

The following would be considered if investigators request approval of prolonged restraint:

1) Restraint devices are not considered normal methods of housing.
2) Restraint devices are not used simply as a convenience in handling or managing animals.
3) The period of restraint is the minimum required to accomplish the research objectives.
4) Animals placed in restraint devices are given training to adapt to the equipment and personnel.
5) Provisions are made for observation of the animal at appropriate intervals, as determined by the IACUC.

6) Veterinary care is provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change will likely necessitate temporary or permanent removal of the animal from restraint.

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

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

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

There have been none

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.

Per the JBVAMC IACUC Policy, multiple major operative survival surgical procedures must be justified and can only be performed in an animal in the context of one specific research protocol. Major operative survival surgery is defined as any surgical intervention that penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection. Laparoscopic surgeries and some procedures associated with neuroscience research (electrode placement) may be classified as major or minor depending on the impact on the animal and will be determined on a case-by-case basis by the IACUC and attending veterinarian.

Based on information presented in the ACORP to the IACUC, the IACUC determines if the multiple major operative procedures are justifiable based on scientific reasons, i.e. is an essential component to the design of the respective research project. Multiple major survival surgeries are allowed only if scientifically justified.

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 are none

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.

There are no protocols approved that require food and/or fluid regulation.

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.

Appendix 3 of the ACORP requires investigators to identify all materials to be administered to any animal in a protocol and indicate whether the material, diluent or vehicle is pharmaceutical or non-pharmaceutical grade. Pharmaceutical grade compounds are defined as those listed as FDA approved or labeled as USP. For all materials, diluents or vehicles that are non-pharmaceutical grade the investigator is required to indicate why the use of the non-pharmaceutical grade formulation is necessary and describe precautions to ensure that the material is suitable for 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.

There are none

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

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

The IACUC does not have a specific policy on the reuse of animals; however, the issue is addressed in the ACORP and the Multiple Major Survival Surgery Policy. In the ACORP investigators are asked whether animals will be euthanatized as part of the planned studies and if the animals are not euthanatized then the investigator is to describe the final disposition of the animals. The disposition of non-naïve animals other than euthanasia is thus reviewed by the IACUC on a case-by-case basis. In accordance with the Multiple Major Survival Surgery Policy, "Multiple major operative survival surgical procedures must be justified and can only be performed in an animal in the context of one specific research protocol."

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.

There are none

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.

There are none

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

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

The IACUC Administrator sends investigators with an approved protocol, an annual renewal request. The annual renewal request form asks the investigator to review their animal care and use protocol and indicate whether they request to continue the protocol or terminate the protocol. If an investigator wishes to continue the protocol, they must indicate if any changes in the protocol are being proposed, whether any unexpected animal welfare concerns have arisen, and if the experiments are providing useful data.

In addition, the annual renewal request requires the investigator to verify completion of VA mandated triennial training and verify all personnel are enrolled in the VA OHSP or the program of the affiliate. Annual renewals are reviewed by the Chair or Vice-Chair and those approved are presented to a quorum of the IACUC at a convened meeting.

Every three years, each investigator with an approved protocol is notified that they must resubmit their protocol to the IACUC for de novo review. All protocols are terminated on the three-year anniversary date.

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

The IACUC reviews the animal care and use program on a semi-annual basis. At least three members of the committee, one of which must be the attending veterinarian, must be present for the programmatic review. Members conducting the programmatic review complete the VA mandated checklist for the semi-annual program review. If program deficiencies are noted they are classified as significant or minor and the Committee will develop a reasonable and specific plan and schedule for addressing each respective deficiency. A significant deficiency is one that is or may be a threat to the health and safety of animals or personnel. The check list is then brought before the IACUC at a convened meeting for review, discussion, and approval via signature. Following approval of the semi-annual program review and facility inspection, the IACUC Administrator schedules a meeting with the Institutional Official to discuss the report, action plan, IACUC departures from the Guide, and any other aspects of the ACUP. This meeting is attended by the Institutional Official, Chief of Staff, attending veterinarian, AO, IACUC Chair, IACUC Administrator /facility manager. Upon completion and approval of the facility and program semi-annual inspection report, a copy is forwarded to VA Central Office. A copy of the last program review report is provided.

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

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

Note: A copy of the last report of these reviews should be included as **Appendix 10**.

The IACUC inspects, on a semi-annual basis, the VMU and JBVAMC laboratories outside of the VMU where animals are taken. At least three members of the committee, one of which must be the attending veterinarian, must be present for the physical walk through of the animal facility and any research area where animals are used. Members conducting the facility inspection then complete the VA mandated checklist for the

semi-annual facility inspection. If facility deficiencies are noted they are classified as significant or minor and the Committee will develop a reasonable and specific plan and schedule for addressing each respective deficiency. A significant deficiency is one that is or may be a threat to the health and safety of animals or personnel. The check list is then brought before the IACUC at a convened meeting for review, discussion, and approval via signature. Following approval of the semi-annual program review and facility inspection, the IACUC Administrator schedules a meeting with the IO to discuss the report, action plan, IACUC departures from the Guide, and any other aspects of the ACUP. This meeting is attended by the IO, Chief of Staff, attending veterinarian, AO, IACUC Chair, IACUC Administrator /facility manager. Upon completion and approval of the facility and program semi-annual inspection report, a copy is forwarded to VA Central Office. A copy of the last facility semi-annual inspection report is provided.

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.

The JBVAMC is registered with the USDA and submits an annual report to the USDA. However, the USDA follows a policy of NOT inspecting VA animal facilities. Moreover, at this time, the JBVAMC does not house any USDA covered species.

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

While accreditation by AAALAC International is normally considered a voluntary process, all VA animal care and use programs are required to obtain and maintain AAALAC accreditation. Additionally, the VA research service, including animal care and use programs, are monitored internally by the VA Office of Research Oversight.

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

Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, any member of the IACUC, and the Chief Veterinary Officer at VA Central Office. Signs are in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern is protected against reprisals. If necessary, the IACUC Chair convenes a meeting to discuss, investigate, and address any reported concern. All reported concerns are brought to the attention of the full Committee. Reported concerns and all associated IACUC actions are recorded in the IACUC meeting minutes. The Committee reports such

actions to the IO and, as warranted, to OLAW and other appropriate regulatory and accrediting agencies.

4. Disaster Planning and Emergency Preparedness [*Guide* p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

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

The VMU staff in conjunction with the attending veterinarian developed an emergency plan for the VMU. The plan focuses on the most likely risks to the animal care and use program as determined by risk analysis. The VMU staff is responsible for the initial response to an emergency including, notifying the attending veterinarian, ensuring the appropriate care of the research animals housed in the facility, and notifying as appropriate key representatives/departments within the JBVAMC. Key representatives/ departments may include the Director of the JBVAMC, the ACOS, Industrial Hygienist, EHS, Radiation Safety Officer, Police/Security, Public Affairs and Engineering.

The Disaster Plan includes a flow chart on type and level of emergency, line of contact, and initial response. Types of emergency situations included in the flow chart include; biologic, chemical and radioactive spills, sever winter storm, infrastructure failure, employee violence, animal activism, bomb threat/terrorist action, tornado fire/explosion and pandemics. As part of the contract with UIC to provide veterinary services, UIC will provide housing space should an emergency arise, which would jeopardize the health and well-being of the animals maintained at the JBVAMC.

II. Animal Environment, Housing and Management

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

A. Animal Environment

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

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

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is

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

Each animal room contains devices designed to measure relative humidity and ambient room temperature. Animal care technicians record daily on a record form the maximum and minimum humidity and temperature. Humidity and temperature are also monitored by an Edstrom Watchdog system and the Engineering Services computerized energy management system.

b. List, by species, setpoints 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]

Temperature set points and/or environmental conditions are maintained within the range recommended by the Guide for each respective species maintained at the JBVAMC VMU. Set points are:

Mice and rats 72+/-2°F
The humidity range for all species is between 30% and 70%.

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]

By IACUC policy, the default method of housing is to pair or group house mice and rats, which allows for behavioral thermoregulation through huddling. In addition, mice are provided nesting material and rats are provided shelters in their cages.

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.

Evidence of changes in ventilation rates are monitored daily by listening for the sound of the supply and exhaust fans, noting abnormally increased odors, and investigating alterations in the amount of air coming from the supply diffusers. Moreover, as part of the semi-annual inspection process rooms are assessed for odors and large air

differentials between animal rooms and corridors. Finally, ventilation rates are checked twice a year by Engineering Services or a contractor, and balanced if necessary.

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

There are none

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

No recycled air is used in animal rooms or primary enclosures.

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).

There are none

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).

Does not apply

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.

Insulated hollow core steel doors provide good dampening of corridor noise to the animal rooms in the animal facilities. Moreover, the hollow core steel doors do a good job containing noise to the cage wash area. Finally, the mechanical space that serves the VMU is not contiguous to the 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.

The IACUC uses the Guide to verify adequacy of space for research animals. Mice and rats are maintained in standard shoebox caging for the respective species. All mice and rats are maintained in static micro-isolator cages.

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

The IACUC has approved an exception to the Guide's floor space recommendations for female plus litter with male (51 sq. in. + 15 sq. in. = 66 sq. in). The exception allows for the use of a trio-breeding paradigm for inbred strains of mice with the institution's current caging system, which provides 66 sq. in. of floor space. The exception was granted based upon a study conducted by the UIC veterinary staff in which various parameters were analyzed over a four-month period from 16 monogamous pairs and 8 trio-breeding groups maintained in 66 sq. in. of floor space. No significant difference was found between the two breeding paradigms for the following parameters: average day to first litter, average number of pups/female/week, average percent of pups surviving to weaning, average number of pups at birth and weaning, average body weight of male breeders, average body condition score of female and male breeders, average weight of pups at weaning, average pup adrenal weights at weaning, average breeder adrenal weights at sacrifice and average fecal corticosterone levels in pups at weaning. It should be noted that though the study was conducted at UIC the caging type, feed and bedding used, and cage processing procedures were essentially identical with how cages are treated and maintained at JBVAMC.

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).

There are none

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).

All mice receive nestletts or other materials to promote nesting behavior. Rats receive a shelter tube.

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

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

The JBVAMC IACUC Policy on Social Housing of Animals Used for Research, Teaching or Testing requires social housing to be the default method of housing unless otherwise justified based on social incompatibility, veterinary concerns regarding animal well-being, or scientific necessity approved by the IACUC.

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.

The IACUC recognizes that there are certain scenarios that would preclude the social housing of animals. The following are general categories of exceptions to the social housing policy and the IACUC approval requirements for each:

Experimental Requirements: When the single housing of a social species is necessitated (other than short term recovery from experimental manipulation) for experimental reasons, a scientific justification/rationale must be provided in the appropriate section of the ACORP and approved by the IACUC as an experimental exception to the institution's social housing policy.

Veterinary Care: The attending veterinarian or designee may require social animals to be housed individually for veterinary medical and/or animal welfare concerns. Exemptions from single housing for veterinary care purposes are documented and reviewed on a regular basis by the veterinary staff. IACUC approval is not required for veterinary care exceptions from social housing.

Exceptions Recognized by the IACUC: A specific justification in the ACORP and case-by-case approval by the IACUC is not required for the following situations, which are considered program wide social housing exceptions based upon standard practices:

1) Separation of aggressive or incompatible conspecifics (The IACUC and attending veterinarian recognize the following categories of animals are aggressive and/or incompatible with conspecifics - (unfamiliar adult male mice and male retired breeder rats and mice)
2) Individual housing due to attrition of cage mates or uneven number of animals
3) Standard practices in breeding colony management that results in the need to periodically house animals individually, including:
   - Single housing breeder males between mating with females,
   - Single housing pre-parturient females,
   - Single housing animals of either sex at weaning when litter makeup contains a single male and/or female at the time of weaning
4) Standard practices in managing surgical procedures or other procedures including:
   -single housing animals up to 14 days for post-operative recovery and observation. The need to single house animals for greater that 14-days post-surgery must be outlined in the approved ACORP.

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

Per the JBVAMC IACUC Policy on Social Housing of Animals Used for Research, Teaching or Testing, "In the absence of other animals, i.e. solitary housing of an individual animal in a room, the policy requires additional enrichment be offered, as appropriate to the species of concern". In terms of standard practice, individually housed mice and rats are maintained in rooms with other animals (like species). This allows for the individually housed animals to have at a minimum visual and olfactory contact with other animals.

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 animal care and veterinary staff provide day-to-day review of the enrichment programs and exceptions to social housing to ensure the well-being of the animal. In addition, the JBVAMC Policy on Social Housing of Animals Used for Research, Teaching or Testing and implementation of the Policy is reviewed by the IACUC once a year as part of the institution's annual policy review process. Finally, experimental exceptions to social housing for mice and rats require triennial review and approval by the IACUC.

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

No special procedural habituation and/or training of animals occur with respect to routine husbandry procedures. Habituation and training of animals to experimental procedures would be study dependent and would be described in the ACORP.

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 are none

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.).

Does not apply

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.

Does not apply

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).

There are none

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

Does not apply

iii. Describe how animals are captured.

Does not apply

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

The standard research diets used within the JBVAMC VMU are Teklad irradiated rodent diet # 7912 manufactured by Envigo Laboratories, Inc., Madison Wisconsin. Custom research diets to meet specific project needs are obtained from commercial vendors such as Envigo, Purina Mills or Research Diets Inc., based upon investigator preference.

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

Standard laboratory animal diets are distributed from the Research Diet Warehouse Building and Teklad Feed Plant in Madison, WI. The warehouse is a completely enclosed, climate-controlled facility. Product is received in the warehouse within two to three days of milling and is rotated and stored using a first-in, first-out inventory rotation system. Feed is received from the manufacturing plant on pallets. Temperature and humidity are monitored and recorded 24 hours a day. Temperature in the diet storage areas does not exceed 70°F.

Laboratory animal diets are stored 18" from any wall and spilled product is kept to a minimum to discourage vermin in the area. The warehouse has a white sanitation stripe around the perimeter of the warehouse to facilitate the daily inspection for vermin. Pest control is provided by a professional pest control company, which makes monthly visits to the facility.

Within the VMU, feed is stored in room (b) (6) on polypropylene pallets at least 8" from the wall. Temperature in this room is maintained at approximately 37°F and humidity ranges between 30% and 70% and pest control is conducted as described below.

In animal housing rooms, feed is kept in lidded polyethylene containers. The container holds one or two bags of food. When the bags of food are empty, bags are

removed, and the container is sanitized. In biohazard rooms, small amounts of food may be maintained in a static microisolator cage, which is labeled with the food type and expiration date.

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).

At this time, special diets are purchased from a commercial source and removed from the food storage room as needed. There are no special food preparation areas within the VMU.

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

Mice and rats are fed ad libitum in wire tops.

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

Milling dates of bagged food are monitored closely. At six months beyond the milling date, bags are discarded. Older food is labeled and used before fresher food. The VMU relies on the quality assurance statement provided by the manufacturers of each food item. If problems are noted either in the appearance of the food or clinical changes in animals suggestive of a nutritional problem, then feed analysis may be performed. Other chemical analysis is performed only at the request of the principal investigator. Representative feeds are tested on a semi-annual basis for microbial contaminates. These samples are sent to the Biologic Resources Laboratory at UIC for microbiological analysis. A record book with test results is maintained and will be made available for site visitors upon request.

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 provided is municipal in origin. Water bottles and sipper tubes are used for rodents. The standard is to sterilize water bottles and water prior to use.

Situations that preclude the sterilization of water include when antibiotics, test substances and alcohol are administered in water.

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

Water is analyzed for heavy metals and microbial agents on a semi-annual basis. Samples are collected aseptically from the water bottle filling station. These samples are taken to the Biologic Resources Laboratory at UIC. The BRL sends some samples to a commercial company for heavy metal testing and conducts microbiological analysis on the other samples. Additional chemical analysis is performed only at the request of the principal investigator. A record book with test results is maintained and will be made available for site visitors upon request.

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

Does not apply

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

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

The standard contact bedding type used for mice and rats at the JBVAMC VMU is one quarter inch heat treated ground corncob Laboratory Animal Bedding, manufactured by Harlan Laboratories, Inc., Madison Wisconsin. A flat white paper cage liner (IsoPad) is used as a contact bedding material in situations where food is collected to estimate food intake or to collect feces for analysis.

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

Bedding is stored in room (b) (6) on bulk trucks at least 8" from the wall. Temperature in this room is maintained at approximately 72°F and humidity ranging between 30% and 70%. Pest control is described below.

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

Corncob bedding is tested on a semi-annual basis for microbial contaminates. These samples are sent to the Biologic Resources Laboratory at UIC for microbiological analysis. Other microbiological or chemical analysis is performed only at the request of the principal investigator. A record book with test results is maintained and will be made available for site visitors upon request.

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.

A temperature-controlled minivan is available for transporting animals.

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

A regular hose sprayer and dedicated floor scrubber machine is used on VMU hallways and corridors only. Hydraulic lift is also used for moving pallets of feed or bedding.

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

i. Bedding/Substrate Change

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

Mice and Rats: solid-bottomed shoebox cages are changed weekly.

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

Per standard operating procedures, sentinel mice and rats are maintained on dirty bedding from the cages of animals within their respective rooms, as part of the VMUs sentinel program to assess the microbial status of the rodents.

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

Soiled bedding is removed from rodent cages in the Cage Wash area (b) (6) (b) (6) in a HEPA filtered medical waste dump station; clean bedding is placed into clean cages in (b) (6) (Bedding Storage).

ii. Cleaning and Disinfection of the Micro- and Macro-Environments

Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and

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

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

There are no IACUC-approved exceptions to the minimum sanitation frequency recommended in the guide.

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).

Water temperatures in the rack and bottle washers are monitored by the daily use of temperature strips and/or manual checks of temperature gauges. Cage wash units also have programmed temperature guarantees, which prevent the completion of a wash cycle should temperatures not reach specific set points. Should a temperature strip not indicate an appropriate temperature was reached during the wash cycle or a washer not complete a cycle due to failure to reach a temperature guarantee then the equipment is re-washed. Should the washer fail to reach appropriate temperatures on the second cycle, the VMU manager is notified and the cause is investigated and corrected by the VMU staff and/or a Washer Solutions service technician.

Washers are tested for effectiveness quarterly by testing cages for microbial contamination after they have been cleaned. A representative cage is sampled in two locations using a standard RODAC plate and the plate is submitted to the Biologic Resources Laboratory diagnostic laboratory at UIC for microbiological analysis. Should gram negative bacteria or more than 38 colonies of gram-positive cocci be noted, additional samples are obtained for testing. If the results are again unacceptable, the cause is investigated and corrected by the VMU staff and/or a Washer Solutions service technician.

b) Describe preventive maintenance programs for mechanical washers.

Washer Solutions conducts quarterly inspections on the cage/bottle washer and Sanitation Strategies conducts quarterly inspections of the chemical dispensing equipment.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]

Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding and refuse are placed in biohazard bags within lidded biohazard containers and transported daily to a pickup area outside of the VMU. These materials are removed by Environmental Management Services for delivery to a company licensed for the disposal of medical waste.

ii. Animal carcasses.

Animal carcasses - Animal carcasses are placed in either a dedicated freezer or refrigerator within the Necropsy room (b) (6). Removal of frozen carcasses is coordinated with Environmental Management Services for pickup by a company licensed for the disposal of medical waste.

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

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

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

The JBVAMC has in-house pest control personnel that can be consulted if evidence of vermin is discovered. The presence of vermin and pests in the VMU is monitored using live traps in rodent rooms and insect boards in storage rooms, support areas, and bathrooms. There is no periodic use of pesticides within the facility. If evidence of an insect/arachnid problem is noted by the staff of the VMU a work order is placed with Environmental Management Services (EMS) to assess and address the problem. Recommendations to address a pest and/or vermin problem are discussed with the facility manager.

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.

Does not apply

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

At this time, no pesticides are used in the VMU. If pesticides are deemed necessary, the investigators would be notified in writing prior to use.

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.

Work-shifts for the two animal caretakers are split in order to provide 7-day coverage. Standard husbandry practices that occur during the week continue over weekends and holidays.

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

Does not apply

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

The facility manager and attending veterinarian are continuously "on-call", and may be reached by telephone. These numbers are conspicuously displayed within the VMU. In addition, for weekends, holidays, and when the attending veterinarian is out-of-town, emergency veterinary care is provided by the BRL/UIC veterinary staff. Investigators and/or JBVAMC animal care staff may contact the UIC on-call veterinarian by calling the BRL/UIC veterinary care emergency telephone number also located at key locations throughout the VMU. The recorded message at this telephone number will inform the investigator or staff member of the veterinarian on-call and how he/she may be contacted. It should be noted that typical weekend coverage at UIC consists of the on-call veterinarian spending Saturday and Sunday mornings at the BRL, hence veterinary support is readily available for a portion of the weekend. During the remaining portion of the weekend, the on-call veterinarian is available by phone.

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).

Rodents may be individually identified by ear notch or ear tag if required by the specific study or requested by the principal investigator. Most rodents are identified at the cage level by a cage card. Primary enclosures for all animals housed within the

VMU are labeled by a cage card. Cage cards are produced the day animals arrive or at the time of weaning.

Each cage card contains the following information: source of animal, species and strain or stock (if appropriate), name and telephone number of the principal investigator, date of birth or approximate age, date of arrival, and the IACUC approved protocol number.

b. Breeding, Genetics, and Nomenclature

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

Most principal investigators at JBVAMC are very experienced with focused research programs and thus are very familiar with their respective models of interest including genetically engineered models. In addition, as part of the veterinary pre-review of the ACORP, investigators are advised on genetic issues and/or model selection by the attending veterinarian.

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

The nomenclature of research animals used is indicated in the ACORP and reviewed by the attending veterinarian and the IACUC.

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

The investigative staff is responsible for monitoring and verifying the genetic integrity of their breeding colonies and to maintain appropriate records. Monitoring methods include tail snips and PCR. Most investigators perform their own PCR tests.

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."

As part of the ACORP (page 7 item M.3), investigators are required to indicate if genetically engineered or modified animals exhibit any characteristic clinical signs or abnormal behavior related to their genotype. If abnormal health or behavioral

considerations are associated with a genotype the investigator is to describe the phenotype.

The investigative, animal care and veterinary staff all play a role in monitoring the health and well-being of all animals housed in the VMU including newly generated genotypes. The animal care staff observes animals daily and the veterinary staff observes all animals at least weekly for health related issues. Should a phenotype that negatively impacts the well-being of an animal be identified, then the investigative, animal care and veterinary staff would look at ways to manage the condition in the context of current husbandry practices and the research study. Depending on the condition, the investigator or veterinary staff would notify the IACUC. It should be noted that as part of the annual protocol renewal investigators are requested to indicate if any unexpected animal welfare concerns have arisen.

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

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

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

1. Animal Procurement

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

Animals housed at JBVAMC VMU are purchased through VA R&D, with the approval of VMU supervisor, or through UIC, with the approval of UIC BRL. Both JBVAMC and UIC use the same criteria, listed below, to establish approved vendors.

1) The vendor quality assurance (QA) program and/or animal or colony health reports.
2) Vendor history with the institution and/or recommendations from colleagues, and clients of the vendor.
3) Results of diagnostics performed on vendor animals.
4) Investigator specifications and availability.

Investigators are advised of the quality of animals available and strongly encouraged to purchase from those suppliers with the most acceptable animals. In addition, the ACORP and UIC animal protocol forms, address purchasing requirements of animals, thus prompting investigator/veterinary interaction on this issue during pre-review of the protocol. Most mice and rats are obtained from commercial vendors having specific pathogen free (SPF) stock. All animals are observed by the animal care staff at the time of arrival. Questionable findings are immediately forwarded to the facility manager and/or attending veterinarian.

It should be noted that the UIC and JBVAMC mouse and rat colonies are of the same health status. As a result, the respective institutions treat each other as an approved source of animals. This allows for the transportation of animals between the respective institution's conditioned colonies without the need for quarantine and/or rederivation.

Animals from non-approved vendors must be pre-approved by the veterinary staff. Pre-approval includes a thorough review of the health status of the rodent colonies from which the animals will be obtained. It should be noted that all quarantine and rederivation procedures are conducted at UIC. Quarantine procedures for SPF mice and rats from unapproved sources include testing and verification of health status at UIC before transfer to the JBVAMC VMU. When supplier reports from unapproved sources indicate the animals are non-SPF, animals are housed in the BRL quarantine room, treated for ecto- and endoparasites, and rederived prior to transfer to the JBVAMC VMU.

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).

1) Transportation of animals between approved commercial sources and the JBVAMC: Animals are transported from approved commercial vendors in vendor operated/leased vehicles to the JBVAMC in shipping containers consistent with the industry standards for mice and/or rats. VMU staff surface decontaminate shipping containers before entering the VMU. All animals from non-approved sources are received by the UIC BRL for quarantine and/or rederivation.

2) Transportation of animals between the JBVAMC and the affiliate institutions: Animals are transported in climate controlled JBVAMC or affiliate institution vehicles in secured microisolator cages or shipping containers consistent with the industry standards for mice and/or rats. Cages and/or shipping containers are surface decontaminated prior to shipment from the JBVAMC. Transportation of animals to an affiliate institution using a VA climate-controlled vehicle includes placement of the cages in a low sided (uncovered) plastic bin (secondary container), in the cargo compartment of the van. The only affiliate institution from which animals can be received is UIC as the colony health status of the other affiliate requires that the animals be quarantined and/or rederived at UIC. Cages and/or shipping containers received from UIC are surface decontaminated at the time of receipt.

3) Transportation of animals outside the VMU but within the JBVAMC: Animals are transported outside the VMU to research laboratories in their primary enclosure. In this case, the primary enclosure is covered to prevent visualization of the animal and only non-patient elevators are used to transport animals between floors.

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.

The following methods are used within the JBVAMC animal care program to monitor for known and unknown infectious agents: clinical assessment, PCR, serology, fecal flotation, peri-anal tape tests, cecal observation, fur pluck, skin scrapings, necropsy and histopathologic assessment.

The health monitoring program for mice and rats utilizes sentinel animals maintained on dirty bedding. Sentinel mice and rats housed in the VMU are tested quarterly by serology and PCR for rodent pathogens, tape test and/or cecal observation for pinworms, fur pluck for ectoparasites, and fecal flotation for helminths.

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

Key components to the JBVAMC VMU Preventive Health Program include: 1) purchase of healthy animals (i.e. from an approved vendor list); 2) the quarantine/ rederivation of animals from non-approved sources; 3) maintenance of mice and rats in sterilized microisolator caging; 4) routine health monitoring of colony animals; 5) diagnostic work-up of selected index cases and health monitoring of sentinel animals; and 6) isolation and or depopulation of animals in the face of a disease outbreak.

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

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

All animals are received at the dock area of the JBVAMC research building by VMU staff. At the time of receipt, the shipping crate is sprayed with quaternary ammonium and the animal care staff examines the crate for signs of damage that may have potentially exposed the animals within to adverse conditions during shipping. Since most rodents are specified as SPF, breaks in the shipping container indicate potential microbial contamination. Dead or diseased animals within crates cannot always be determined upon receipt at the receiving dock. If such animals are found when the shipping crate is opened, the vendor is contacted as soon as possible. If a crate defect is noted and/or dead/diseased animals are found then the head technician and/or facility manager are notified and the attending veterinarian and/or designee is consulted and a decision is made to either refuse the order, or place the animals in quarantine or euthanatize the animals. The investigator is also notified and consulted when such cases arise.

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.

Specific pathogen-free rodents from the approved vendor list are not isolated in a specified quarantine area. However rodents do complete the conditioning period within the room that will serve for long-term housing. Newly arrived animals are monitored for shipping-related distress.

The JBVAMC contract with UIC to provide veterinary services/support includes a provision for UIC to provide quarantine/rederivation support for the JBVAMC animal care and use program. Quarantine procedures for SPF mice and rats (animals from colonies free of pathogens excluded at JBVAMC) from unapproved sources include testing and verification of health status at UIC before transfer to the JBVAMC VMU. When supplier reports from unapproved sources indicate the animals are non-SPF (i.e. animal colonies have pathogens excluded at JBVAMC), animals are housed in the BRL quarantine room, treated for ecto- and endoparasites, and rederived using a cross-foster surrogate mother rederivation process prior to transfer to the JBVAMC VMU. Testing procedures may include serology, PCR, fur pluck examination and fecal floats.

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

It is recommended that investigators allow for a minimum three-day acclimation period following shipment of animals.

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

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

Animals are separated according to species. Rodents from various sources may be housed in the same room; however, only animals of equivalent health status are combined.

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

At this time mice and rats are only housed in separate animal rooms.

c. Describe isolation procedures and related facilities for animals.

The vast majority of clinical cases are of individual animal concern, and therefore do not require isolation of ill animals. If a contagious agent is suspected, then several

options exist. For colonies of animals, in which the entire colony was likely exposed prior to the detection of clinical illness, the room is placed on isolation status and appropriate husbandry measures are taken to minimize spread within the VMU. Alternatively, animals may be relocated to a clean, unoccupied room for isolation. Finally, animals may be euthanatized/depopulated if the attending veterinarian and/or designee determined that this is the only way to control a disease outbreak. In any case, animals or colonies under isolation or quarantine are serviced only after all "clean" rooms. Entry into a clean room after a "contaminated" room (such as one in isolation) requires staff to not only change PPE but scrubs. Investigators would also be notified of the isolation of their animals and the appropriate precautions to take to minimize cross contamination within the facility. In the case of the need to euthanatize an animal or depopulate a colony of animals the investigator would be notified by the attending veterinarian and/or designee.

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.

1) All animals are visually inspected daily by a designated VMU animal caretaker, and once weekly by a veterinarian.

2) VMU animal caretakers are experienced animal husbandry technicians who obtain continuing education from a web-based training program every three years, as well as from supplemental training offered by a veterinarian.

3) When an illness or abnormality is observed, the animal caretaker identifies the cage with a "Health Monitoring and Treatment" card, initiates a Clinical Incident Form located in a binder, which is stored outside the facility manager's office, and notifies the facility manager. A member of the animal care staff and/or facility manager then notifies the attending veterinarian or designee via telephone or email the same day. Per attending veterinarian or designee discretion, based on case severity, the illness or abnormality will be attended to within the same day (e.g. dystocia, labored breathing) or within a week (eg. mild dermatitis). Once the case is seen by a veterinarian, the veterinarian records the findings and plan on the Clinical Incident Form, briefly on the "Veterinary Oversight Sign Off Sheet", and communicates via email or verbally with the investigator staff and notifies the VMU facility manager and caretakers of the communication. In the case a veterinarian identifies an illness or abnormality, the veterinarian identifies the cage

with a "Health Monitoring" card, records the findings and plan on the Clinical Incident Form, briefly reports the finding and plan on a "Clinical Veterinary Oversight Record", and communicates via email or verbally with the investigator staff and notifies the VMU facility manager and caretakers of the communication. If the plan includes action required by the investigator staff by a certain time, per veterinary discretion, and the action is not done by the specified time, then a VMU caretaker, facility manger or a veterinarian will undertake the treatment action, including euthanasia.

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

The VMU staff (facility manager or animal caretakers) and veterinarians (attending or designee) contact investigator staff as needed regarding animal health and protocol related issues. Communication methods, depending on the issue, include verbal communication in person or via telephone, or email with all parties (veterinarians, VMU staff, investigator staff) copied. "Health Monitoring" cards also indicate cages with an illness or abnormality and original Clinical Incident Forms are available for veterinarians, VMU staff and investigator staff to read and record findings or treatments as appropriate.

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

The JBVAMC VMU Preventive Health Program is composed of the purchase of healthy animals (i.e. from an approved vendor list) or received from UIC after quarantine or rederivation. In addition, routine health monitoring of colony animals, diagnostic work-up of selected index cases and health monitoring of sentinel animals is conducted by the VMU and veterinary staff. Unusual or unexpected illnesses or deaths that may affect the health of a given colony are investigated. Sentinel mice and rats housed in the VMU on dirty bedding are tested quarterly by serology and PCR for rodent pathogens, tape test and/or cecal observation for pinworms, fur pluck for ectoparasites, and fecal flotation for helminths.

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

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

The facility manager and attending veterinarian is continuously "on-call"and may be reached by telephone and/or pager. These numbers are conspicuously displayed within the VMU. In addition, for weekends, holidays, and when the attending veterinarian is out-of-town, emergency veterinary care is provided by the BRL/UIC veterinary staff.

Investigators and/or JBVAMC animal care staff may contact the UIC on-call veterinarian by calling the BRL/UIC veterinary care emergency telephone number also located at key locations throughout the VMU. The recorded message at this telephone number will inform the investigator or staff member of the veterinarian on-call and how he/she may be contacted. It should be noted that typical weekend coverage at UIC consists of the on-call veterinarian spending Saturday and Sunday mornings at the BRL, hence veterinary support is readily available for a portion of the weekend. During the remaining portion of the weekend, the on-call veterinarian is available by phone.

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

Per the JBVAMC IACUC Policy on adequate veterinary care, "The attending veterinarian and/or his designee are responsible for providing and/or ensuring that all animals housed in the VMU receive appropriate medical and emergency care. Protocol created or related conditions are the responsibility of the investigator who in conjunction and/or consultation with the veterinarian should provide the necessary treatment and/or support. In the case of a situation in which an animal's health and welfare are in jeopardy and the investigator is not available or if the investigator and veterinarian cannot reach a consensus on treatment and/or course of action, the veterinarian has the authority to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or euthanatize the animal. If a situation arises in which the veterinarian and investigator are unable to reach a consensus on treatment and/or course of action the veterinarian has the authority to ensure appropriate animal welfare/veterinary care and the matter is to be reported to the IACUC for review and consideration".

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.

Health reports and other shipping documentation that accompany rodent shipments, VMU sentinel serology and PCR results, Clinical Incident Forms, and perioperative monitoring sheets are maintained by the VMU facility manager in record books. During the immediate post-operative period, rodent perioperative records are maintained in the animal housing room.

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 record books are in administrative support areas in the VMU except for open Clinical Incidence Forms which are located outside of the VMU facility manager's office. The attending veterinarian and/or designee, VMU facility manager and animal caretakers have access to all records, whereas investigator staff have access to records that are pertinent to their work.

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

The attending veterinarian and/or designee are responsible for reviewing the documents and using the information to assess animal and colony health, postoperative care, and planning and recording an appropriate course of treatment including euthanasia and necropsy in the case of ill animals.

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

a. In-house diagnostic laboratory capabilities.

The VMU relies on the clinical laboratory within the UIC-BRL to perform complete blood counts, clinical chemistries, bacterial culture and sensitivity, endo- and ectoparasite assessments and to process tissue, blood and feces for histopathology, serology and PCR respectively.

b. Commercially provided diagnostic laboratory services.

Commercial diagnostic laboratories, including IDEXX BioResearch and Charles River Laboratories, are used to support the rodent Preventive Health Program and include serologic and PCR assessment for murine pathogens.

c. Necropsy facilities and histopathology capabilities.

A dedicated necropsy room(b) (6) is maintained in the VMU. This room contains a stainless-steel necropsy table and sink equipped with a disposal unit. Accessory equipment includes tables, surgical lights, dedicated freezer, and specimen storage. Histology/pathology requests for in-house cases and some investigator-related projects are sent to Charles River Laboratories, IDEXX BioResearch or the pathobiology/histopathology laboratory at the University of Illinois, College of Veterinary Medicine, Champaign-Urbana.

d. Radiology and other imaging capabilities.

There are none

5. Drug Storage and Control

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

Controlled drugs used in the JBVAMC must be obtained from JBVAMC Research Pharmacist located in the in-house VA Pharmacy. The VA Pharmacy will load the Controlled drugs in the PYXIS unit (Automatic Dispensing Cabinet, ADC) located in VMU Room (b) (6)

Non-controlled drugs used in the JBVAMC may be obtained from the in-house VA Pharmacy, commercial suppliers or the UIC BRL surgery service. There are no specific security storage requirements for non-controlled drugs.

b. Describe record keeping procedures for controlled substances.

Summary of the approval, procurement and use of controlled substances with the JBVAMC is provided below.

a. The specific use of controlled substances for animal research must be detailed in the Animal Component of Research Protocol (ACORP Item X1a), UIC/VA Addendum documentation or in subsequent modifications.
b. After the protocol (or modification) is approved by the JBVAMC Institutional Animal Care and Use Committee (IACUC) and the JBVAMC R&D Committee (IACUC/ACOS approval letters uploaded to IRBNet), the PI or authorized staff that are listed on the approved protocol (or modification) fills out the Pyxis® User Form. This form requires signature of the Pyxis® User, as well as the VMU Supervisor.
c. The Pyxis® User Form, IACUC/ACOS Approval Letters and documentation of the specific controlled substances to be used will be supplied to the Research Pharmacist.
d. The Authorized Pyxis® User is responsible for scheduling training with the JBVAMC Research Pharmacist on documentation and use of the Pyxis® system, in order to be allowed access to the Pyxis.
e. Approximately 2 weeks prior to the use of an approved controlled substance for animal research, a written order on **VA Form 10-2321** must be provided to the JBVAMC Research Pharmacist.
f. Controlled Substances will be loaded into the Pyxis® under their respective protocol number and will only be able to be removed for use in the associated study.
g. Drugs must be used on the same day the vial is opened and any unused wasted.
h. Inventory will be completed every 72 hours (Monday-Wednesday-Friday) by Authorized Pyxis® Users. A controlled substance inspector will conduct random and unannounced inspections of the Pyxis® on a monthly basis. The inspection report will include all identified discrepancies, as well as identified areas of vulnerability.

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

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

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

The IACUC requires a detailed description of all surgical procedures, including pre- and post-operative plans as a component of a completed ACORP. This detailed description is reviewed by the attending veterinarian as part of the veterinary pre-review and by the IACUC as part of the ACORP approval process.

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.

Building	Room	Survival/Non-Survival	Species	Activity	Procedure	Equipment
(b) (6)	(b) (6) (VMU)	Minor Non-Survival	Rat	Moderate	Vascular Cannulation and blood pressure monitoring	Anesthesia machines, cauterization probe, pulsoximeter, temperature controlled surgical table, ceramic heater, water circulating heating pads,

						ECG and blood pressure monitor
(b) (6)	(b) (6)	Major Non-Survival	Mice	Light	Liver perfusion for hepatocytes isolation	
(b) (6)	(b) (6) (BSL-2 Room)	Major Survival	Mice	Light	Closed loop bowel perfusion	Isoflurane machine
(b) (6)	(b) (6)	Major Survival	Mice	Light	Laparotomy	Isoflurane machine
(b) (6)	(b) (6)	Major Surgery	Mice	Moderate	Knee injury	
(b) (6)	(b) (6)	Major Surgery	Mice	Light	Brain cannulation	
(b) (6)	(b) (6)	Major Surgery	Rats	Light	Brain cannulation	Isoflurane Machine
(b) (6)	(b) (6)	Major Surgery	Mice	Light	TBI	Isoflurane Machine
(b) (6)	(b) (6)	Major Non-Survival	Mice	Light	Brain Perfusion	

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).

Per the IACUC Policy on Major Multiple Survival Surgical Procedures, "a major operative procedure is defined as any surgical intervention that penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic function or involves extensive tissue dissection or transaction. Laparoscopic surgeries and some procedures associated with neuroscience research (electrode placement) may be classified as major or minor depending on the impact on the animal. The IACUC will determine on a case-by-case basis how the laparoscopic or neuroscience procedure is classified based on the extent the procedure penetrates or exposes a body cavity, produces substantial impairment and/or the degree of tissue dissection".

b. How is non-survival surgery defined?

From a policy standpoint, a specific delineation between non-survival and survival procedures has not been defined, but by practice, any procedure that does not result in the recovery of an animal from anesthesia is considered a non-survival procedure.

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

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

According to JBVAMC IACUC policy, all survival surgery is performed using aseptic technique. This involves appropriate animal preparation, including removal of hair and disinfection of the surgical site. Aseptic technique also includes the use of gloves, clean lab coat or gown, and sterile instruments. In addition, a cap and mask may be donned to prevent contamination. Only sterile instruments, equipment, and other surgical supplies have contact with the surgical site.

The surgery appendix in the ACORP (Appendix 5) requires not only a description of the surgical procedure but also a description of the aseptic techniques that will be utilized to support the surgical procedure. The description on aseptic technique includes details on hair clipping, skin preparation and draping. Additionally, the ACORP requires the investigator/surgeon to detail the steps taken to maintain sterile technique, which include maintaining a sterile field, sterile instruments, and the donning of sterile gloves.

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.

Investigators at the JBVAMC use either steam autoclaves or hot bead sterilizers to sterilize surgical instruments before use. Because the tip is usually the only part of the instrument that is in contact with the tissue/organ in rodents, it is considered acceptable to wash instruments and sterilize the tips using a hot bead sterilizer prior to surgical use. The VMU maintains a hot bead sterilizer for investigator use. At this time, liquid sterilants are not used to sterilize surgical instruments.

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

For serial surgeries in rodents or lower vertebrates, packs containing multiple sets of instruments may be used so instrument packs do not need to be re-sterilized between animals. Alternatively, instruments may be wiped clean of tissue and debris and the tips sterilized using a hot bead sterilizer between animals.

d. Indicate how effectiveness of sterilization is monitored.

Investigators are requested to use temperature sensitive tape as an indicator that the pack and/or instruments are sterilized by autoclaving.

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

The VMU does not support a centralized surgical program. The VMU does have a hot bead sterilizer and water circulating heating pad, which are available to investigators

performing surgical procedures within the VMU. In addition, the VMU has a portable 3 chamber isoflurane machine, with built in scavenging unit (VetEquip). All anesthesia machines are certified annually.

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.

Research staff that performs surgery on rodents is required to assess the depth of anesthesia prior to initiation of the surgical procedures and intermittently throughout the procedure. This is accomplished primarily by assessing response to toe pinch or other manipulation, respiratory rate, and color of skin/tissue. Research staff performing survival surgical procedures is required to document monitoring on the rodent surgical record. There is one investigator conducting prolonged non-survival surgical procedures, and the monitoring documents are maintained on the computer, as part of their research records.

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.

Research staff is required to provide postoperative care. At the time of surgery, the investigator makes a notation of the surgical procedure and date on a card placed behind the cage card. The investigator places the small animal surgical record in a plastic sleeve in the animal room. Monitoring and administration of analgesics, per the Rodent Surgical Classifications and Analgesic Guidelines, are performed and recorded by the investigator on the post-operative monitoring portion of the rodent surgical record. Briefly, surgical procedures are classified per the level of invasiveness and expected level of pain. Depending on the classification (1-4), animals are monitored by the research staff for 2-3 days following the day of surgery. All animals, regardless of classification, are monitored by the research staff twice during the second week following surgery. The veterinary staff observe the animals a minimum of once during the first week following surgery and the animal care staff monitor the animals daily.

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

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

The IACUC and the attending veterinarian classify research protocols based on the potential level of pain or distress included in the VA-mandated ACORP, based on the USDA categories of pain and distress.

In addition, the veterinary, VMU and research staff continually assesses protocols and their potential to cause pain and distress through the observation of ongoing research protocols.

Whenever unanticipated findings in an animal occur such as changes in behavior, reduction in eating or drinking, reluctance to ambulate, rough hair coat, hunched posture, reduced activity, etc., these are communicated by the VMU or research staff to the attending veterinarian and/or designee for assessment and evaluation.

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

Investigative Staff:
To obtain ACORP approval, the investigator staff must complete online training. The online training includes an overview on how to recognize pain and distress in mice and rats, the only species used at the JBVAMC.

Animal Care Staff:
Animal care technicians are responsible for daily monitoring of animal well-being. Training of animal care technicians, including identification of signs of pain and distress, is accomplished through one-on-one training by veterinarians, the facility manager, and more experienced technicians. Additionally, members of the animal care staff have taken part in ALAT and LAT training courses. Training topics as part of these courses include normal behavior and the signs of animals experiencing pain and distress.

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

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

Mice: isoflurane, ketamine, xylazine, buprenorphine, EMLA cream (Lidocaine 2.5% and prilocaine 2.5%).

Rats: isoflurane

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

All ACORPs must be pre-reviewed by the attending veterinarian. During this review the attending veterinarian can assess protocols for adequate analgesia and anesthesia. The IACUC, which includes a certified veterinary technician in the department of anesthesiology, also reviews ACORPs for the adequate use of analgesia and anesthesia. Finally, the IACUC has guidelines on rodent surgical classifications and analgesics to assist investigators in determining type, frequency and duration of analgesic use following a surgical procedure as well as monitoring frequency.

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

The research staff is responsible for monitoring the effectiveness of analgesics. The effectiveness of analgesia or need for additional analgesia is determined by monitoring animals postoperatively for signs of pain such as weight loss, hunched posture, and reluctance to ambulate.

Research staff is also required to complete a small animal surgical form, which is maintained in the animal room for the first 2-3 weeks following a survival surgical procedure. This form, which includes a post-operative monitoring section, allows VMU and veterinary staff to readily identify animals that have undergone a surgical procedure and assess the animal's post-operative condition.

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

There are no protocols at this time using neuromuscular blocking agents. In cases where they are used the investigator must continuously monitor the animal's heart rate and/or blood pressure in order to identify increases indicating more anesthesia is necessary.

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

Anesthesia machines are checked and calibrated annually. A record book with annual anesthesia machine maintenance certifications is maintained in the veterinary medical unit.

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.

Mouse: CO2, isoflurane or ketamine/xylazine (followed by a secondary method to ensure death, cervical dislocation or exsanguination), decapitation with and without anesthesia
Room: (b) (6) (BSL-2), (b) (6)

Rat: CO2 (followed by cervical dislocation), Isoflurane (followed by exsanguination)
Room: (b) (6)

Rat: CO2 (followed by cervical dislocation), Isoflurane (followed by decapitation or exsanguination during perfusion)
Room: (b) (6)

The CO2 Euthanasia guidelines take into account the need for longer exposure time for neonates less than 7 days.

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

The secure flow meters of the VMU centralized CO2 euthanasia stations are checked at least weekly to ensure that 30% of chamber volume is displaced per minute. In addition, the cervical dislocators are checked for functionality.

For decapitation without anesthesia for mice, the scissors are sharpened on a regular basis and replacement ordered if deemed necessary. The frequency is determined by level of use.

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

Death is confirmed by absence of heartbeat, respirations, and corneal reflex.

For mice and rats, the use of a secondary physical method of euthanasia is required. All central CO_2 euthanasia stations and the BSL-2 room are equipped with a cervical dislocator to facilitate use of a secondary method to ensure death.

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.

The VMU is located on (b) (6) [redacted]. See Appendix 3; Facility Floor Plan for JBVAMC, VMU. The oversight of day-to-day operations of the

facility is provided by the Facility Manager and two full-time animal care technicians. Program oversight is provided by the attending veterinarian and the IACUC.

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

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

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

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

1. The VMU is a single corridor, barrier facility located (b) (6) (b) (6) See Appendix 3; Facility Floor Plan for JBVAMC, VMU.

2. The research laboratories of JBVAMC are all located in Building (b) (6) All laboratories are connected to the VMU through research dedicated hallways or through a service elevator. No animals are maintained in a laboratory outside the VMU.

3. Housing is considered to be barrier. Rodents are maintained in sterile static microisolator caging. Cages are changed in either a biosafety cabinet or animal transfer station. There is one dedicated room for rodents infected with BSL-2 agents. Rooms are assigned on an as need basis when high risk chemical agents are used.

4. Animal rooms are equipped with insulated, hollow-core, metal doors. Floors are painted epoxy or monolithic. Walls are constructed of concrete blocks, plaster or drywall, painted with latex-alkyd enamel. The ceilings within the animal rooms and the Cage Wash area are plaster or drywall painted with latex-alkyd enamel paint. Ceilings within the corridor are suspended fiberglass panels.

5. The VMU has a designated biohazard room with a class II biosafety cabinet.

6. The JBVAMC VMU Facility Manager/ IACUC Administrator approves access entry into the animal housing area. This is through a key card access system. There are two card access points one must go through to gain access to the VMU. The first is at the level of the elevator and the (b) (6) . The second is between the (b) (6) research wing and the VMU. In addition, the VMU has six security cameras in the facility which are linked to JBVAMC security. Video surveillance is 24/7.

7. There are no outside windows within the animal housing areas.

8. There are no storage facilities for hazardous materials except for ethanol which is stored in a flame-resistant cabinet within the VMU in room (b) (6). Bulk storage of disinfectants is in room (b) (6)

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.

There are none

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.

There are none

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. Power [*Guide*, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

The VMU has limited access to emergency power. Red outlets are available in some rooms for use of external lighting and small pieces of equipment (animal transfer stations, heaters, etc.). In the event of a power outage, HVAC systems shut down and the animal rooms become static. The VMU has battery operated lanterns to provide temporary lighting.

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 system malfunctions that have resulted in animal loss and/or health problems.

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.

Room (b) (6) is used to support the study of metabolism using specialized calorimetric caging equipment. The acrylic cages are hand washed with bactericidal soap after each use (up to 72 hours).

Room (b) (6) – Bruker LF50 Whole Body NMR – The acrylic restrainer tubes are hand washed with bactericidal soap after use.

Room (b) (6) – Two Rodent Temperature Control Chambers – walls of units will be disinfected with LabSan while shelving cleaned in the cage washer.

Room TBD, could contain the following core behavioral laboratory equipment, Morris Water Maze, an elevated maze, light/dark box and a video camera for recording. The equipment will be disinfected with LabSan after each use.

Room (b) (6) IVIS Imaging System, interior cabinet is disinfected with LabSan after each use.

2. Other Animal Program Support Facilities

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

There are none

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

Appendix 1: Glossary of Abbreviations and Acronyms

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

Abbreviation/Acronym	Definition
ACORP	Animal Component of Research Protocol
ACOS	Associate Chief of Staff
ACUP	Animal Care and Use Procedures
AO	Administrative Officer
BRL	Biological Resources Laboratory
EHS	Environmental Health Service
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
JBVAMC	Jesse Brown VA Medical Center
NU	Northwestern University
OHSP	Occupational Health and Safety Program
OLAW	Office of Laboratory Animal Welfare
PAPR	Powered Air Purifying Respirator
RSC	Research Safety Committee
RSO	Radiation Safety Officer
R&D	Research and Development
SRS	Subcommittee for Research Safety
UIC	University of Illinois Chicago
USDA	United States Department of Agriculture
VA	Veteran Affairs
VMU	Veterinary Medical Unit

Appendix 2: Summary of Animal Housing and Support Sites

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

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft^2, m^2, or acreage for animal housing**	**Approx. ft^2, m^2, or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
(b) (6)	(b) (6)	2200 ft^2	6600 ft^2	Mice, Rats	Mice: 1126 Rats: 5	(b) (6), Facility Manager, VMU
Satellite Housing Facilities Total (Expand in Table 17)						

Totals:	**2200** ft^2	**6660** ft^2
Total animal housing and support space:	**8860** ft^2	
	(please specify ft^2 or m^2)	

Appendix 2: Summary of Animal Housing and Support Sites

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

Appendix 3: Line Drawings

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

(b) (6)

(b) (6)

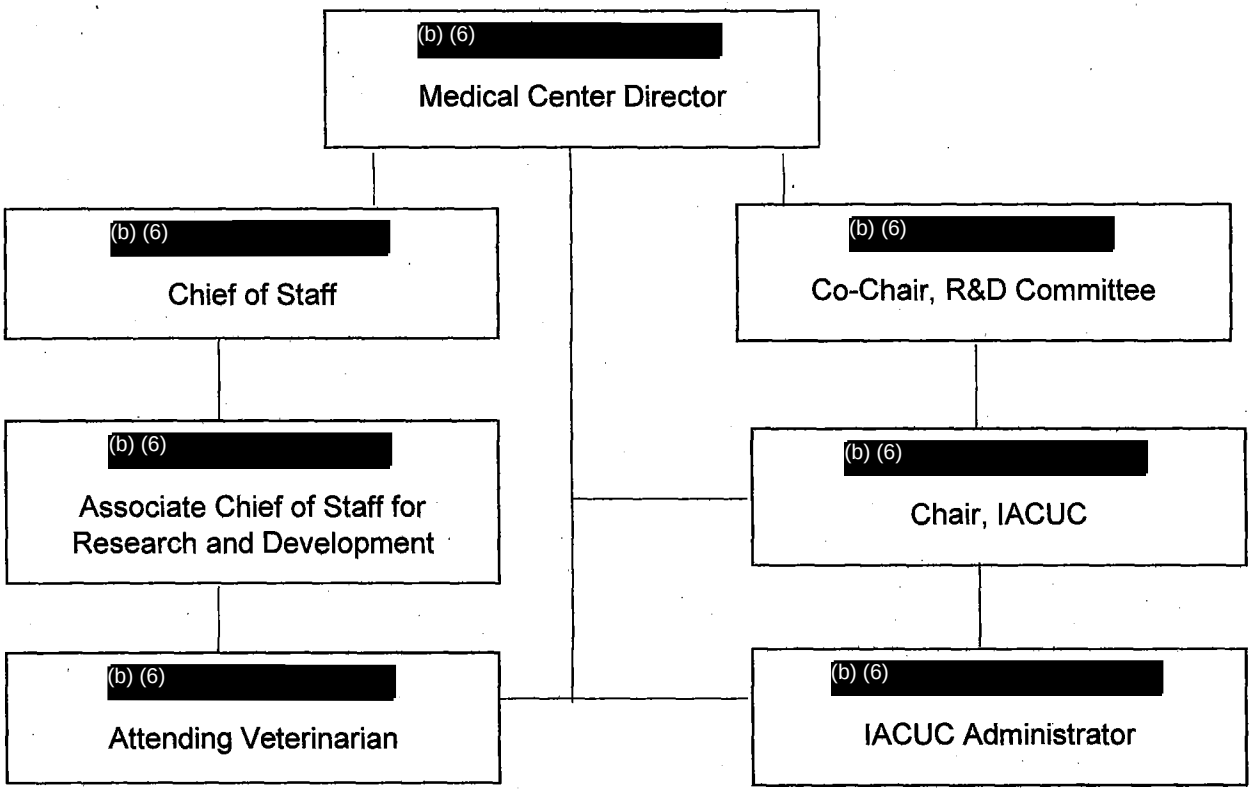
(b) (6)

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.

INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

1. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:



NOTE: As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

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)
Gut-liver cross talk in bile acid induced diarrhea Mice	#19-20	(b) (6)	Mice	8368	C and D					X	
Mechanisms and Regulation of Intestinal Cholesterol Transport	#18-06	(b) (6)	Mice	3492	C and D					X	
Role of intestinal SREBP2 in cholesterol homeostasis	#20-08	(b) (6)	Mice	3432	C and D						
Regulation of susceptibility and severity of inflammatory diseases of the central nervous system by novel innate immune signaling pathways in human myeloid cell	#19-16	(b) (6)	Mice	666	C and E					X	X

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)
The role of Dynamin-2 (Dnm2) in hematopoiesis and phagocyte function during stress	#20-10	(b) (6)	Mice	3798	C and D						
Tumor suppressor function of SLC26A3/DRA	#20-07	(b) (6)	Mice	716	B, C and D					X	
Regulation of Ion Transport in Mouse Models of Colitis	#20-03	(b) (6)	Mice	7285	B, C and D					X	
Role of a Novel Gut Microbial Metabolite Receptor in Colon Carcinogenesis	#19-28	(b) (6)	Mice	167	C and D					X	
Chloride Transporter Downregulation in Infectious Diarrhea	#19-17	(b) (6)	Mice	3395	B, C and D					X	
Mechanisms of NaCl Absorption in the Mammalian Colon	#19-25	(b) (6)	Mice	2720	B, C and D	X				X	
Intestinal Anion Exchangers: Function & Regulation	#18-20	(b) (6)	Mice	10,314	B, C and D					X	
JBVAMC Rodent Holding Protocol	#18-14	(b) (6)	Mice and Rat	4200	B, C and D						
Sentinel Animal Testing Program	#19-01	(b) (6)	Mice and Rat	382	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)
1 PARP-mediated gene regulation in alcohol drinking behavior	#18-02	(b) (6)	Mice	1068	C and D	X					
Intestinal 5-HT Transporter: A novel therapeutic target for GI disorders	#19-31	(b) (6)	Mice	2845	B,C and D					X	
SERT-AhR Axis in intestinal inflammation	#18-16	(b) (6)	Mice	3786	C, D	X				X	
Low-intensity vibration to improve healing of chronic wounds	#18-10	(b) (6)	Mice	5721	B and E	X				X	
Strain dependent NASH development	#18-03	(b) (6)	Mice	448	C						
Hormonal control of liver metabolism	#19-12	(b) (6)	Mice	1651	C and D					X	
Hormonal control of NASH development and progression	#19-05	(b) (6)	Mice	1175	C and D					X	X

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 Novel Role of DRA in IBD pathogenesis	#19-06	(b) (6)	Mice	1624	B, C and D					X	
Cinnamon and its metabolite sodium benzoate in Parkinsonism	#18-08	(b) (6)	Mice	1334	B and E					X	
Cinnamon and traumatic brain injury	#19-27	(b) (6)	Mice	1992	B,C and D	X					
Cellular Signaling in Alcoholism	#18-18	(b) (6)	Rat	756	C and E	X					
Epigenetic Regulation of Intestinal Na+/H+ Exchanger-3	#18-09	(b) (6)	Mice	218	C and D						
Regulation of Intestinal Sodium Absorption in Health and Disease	#19-26	(b) (6)	Mice	1064	B, C, and D					X	
Osteoarthritis and Knee Joint Pain	#18-04	(b) (6)	Mice	944	B,C,D,E	X				X	
Osteoarthritis and Knee Joint Pain - Pazopanib	#18-13	(b) (6)	Mice	2330	C, D, and E	X				X	
Novel strategy to enrich brain DHA through diet; Potential application for the prevention of Alzheimer's disease	#19-09	(b) (6)	Mice	638	B and C					X	

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)
Regulation of Hepatic Gene Expression and Metabolism	#20-04	(b) (6)	Mice	1031	B, C and D					X	
Lipid emulsion infusion to attenuate organ damage after hemorrhagic shock	#18-17	(b) (6)	Rat	66	D						
Modeling perioperative troponin leak	#17-07	(b) (6)	Rat	57	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

Category B- Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. Non-invasive observation only of animals in the wild.

Category C- Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs.

Category D- Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.

Category E- Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.

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

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use
Mice	5445		
Rat	42		

[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).

1) IACUC Employee Health Questionaire

2)Occupational Health Brochure

JBVAMC R&D Admin/IACUC
Veterinary Medical Unit (VMU) Questionnaire
Attn: Employee Health

*Name*_____ *Supervisor*_____

Occupational History & Standard Hospital Requirements:

What species of animals are you exposed to at work? _____
Frequency of contact? _____
What chemicals are you exposed to at work? (Please detail) _____
Have you been tested for TB in the past year? Y N
If Yes, please indicate when? _____ What were the results? *(Circle one)* Positive or Negative
Have you received a tetanus booster in the past 10 yrs? Y N
If Yes, please indicate when? _____
For those individuals currently working in the VMU, have you experienced any of the following?
Change in your health status that may make you more susceptible to infection? Y N
Change in your pulmonary health status that may affect your use of a face mask? Y N

- If you are experiencing chills, fever, cough, bloody cough, night sweats, and/or unexplained weight loss (AS RELATED TO TUBERCULOSIS symptoms) please see/make appointment with the Occupational Health Nurses.
- If you are enrolled at your affiliate you will need to schedule an appointment with that Occupational Health Nurse.

Protective Clothing and Hygiene Practices:

When working with animals, do you always wear:

gloves	Y	N	gown/lab coat	Y	N
mask	Y	N	protective eyewear	Y	N

Do you perform the following after handling animals at work?

wash hands	Y	N	shower/change clothing	Y	N

Have you been issued & do you wear a N-95 or respirator? Y N

Hypersensitivity:

Do you have any allergies? Y N If yes, please list: _____
Are you currently taking medications for your allergies? Y N
If yes, please list: _____

*****

I certify that the information provided above is true to the best of my knowledge. I understand this review is a generalized review aimed for ensuring a safe working environment. I understand I must immediately go the EHS or ER if I have a reaction/ bite/scratch to any animal or agent within the animal handling area. I understand that I am expected to adhere to Federal research/occupational health & safety regulations & failure to do so will result in revocation of my access to the VMU. I understand that I must re-submit the Annual Questionnaire upon changes to my health status.

Print Name_____ Signature_____ Date: _____

Israel Rubinstein, MD
ACOS, R&D Signature _____ Date: _____

JBVAMC, R&D

OCCUPATIONAL HEALTH PROGRAM FOR INDIVIDUALS WITH ANIMAL CONTACT

This document describes the *JBVAMC Occupational Health Program for Individuals with Animal Contact.* It contains information on health concerns associated with working in a laboratory animal facility including zoonotic diseases, animal bites and scratches, animal allergies, and hazardous agents.

The *Guide for the Care and Use of Laboratory Animals* and the *Public Health Service Policy on the Humane Care and Use of Laboratory Animals*, and the *VHA Handbook* require that an occupational health program be part of an institution's overall animal care and use program. The purposes of this program are to protect personnel, protect the animals used in research, and to assure compliance with regulatory and funding agencies. The program is based upon the recommendations of the *Guide for the Care and Use of Laboratory Animals* and the NRC publication on *Occupational Health and Safety in the Care and Use of Research Animals.*

Who Must Participate in the Program?

All VA employees are enrolled in the JBVAMC OHSP. For those individuals working with animal contact as part of an approved animal use protocol at JBVAMC VMU, they are required to participate in the JBVAMC OHSP (or be enrolled in an affiliates [NU or UIC] OHSP, if they have WOC status). Participation extends to animal care staff, investigators, laboratory assistants and students and engineering staff. Enrollment in an OHSP is required to gain access to JBVAMC VMU animal facilities. The level of participation in the program is determined through a risk analysis conducted by JBVAMC Employee Health Service (EHS) staff, based on the species handled and research conducted.

The costs of the basic components of the program are covered by the institution with no additional expense to the investigator. These components include the initial and periodic health assessments, including tetanus immunization, if required.

Risk Levels

For research staff, there are four risk levels, defined as low, mild, moderate, and high. **Low risk** includes personnel who have no direct contact with mammals, including physical plant employees, contractors, and visitors. The **mild risk** consists of personnel who work with the mice and rats, the primary species housed at JBVAMC VMU. The **moderate risk** level is defined as those individuals in the mild risk category who have a condition that requires more frequent assessment by EHS. For example, personnel with a history of allergies, immunosuppressive medical condition or drug regimen, or pregnancy may warrant inclusion at this higher risk category. The high risk level is reserved for research staff that work with nonhuman primates (which are not part of the

JBVAMC Animal Care and Use program and therefore will not be specifically addressed in this brochure).

Administration of the Program

The JBVAMC VA veterinary staff, EHS, IACUC, and Research and Environmental Safety R&D Subcomittee (RSSC) each have a role in ensuring compliance with the occupational health program and ensuring the health and safety of all individuals in contact with animals through VA programs. The VMU Cooridinator or desginee provides species-specific information in an orientation session. At this time, the VMU coordinator explains the occupational health program and provides enrollment forms to the individual requesting access to an animal facility. EHS conducts a health assessment and determines the level of risk posed by the animal species and type of research. The IACUC evaluates and approves the addition of new personnel to an animal use protocol and verifies completion of on-line training. The RSSC evaluates and approves safety aspects of animal care protocols. Each of these components must be completed for an individual to gain access to an animal facility.

Risks in the Animal Research Facility

This section of the brochure focuses on general methods to prevent disease transfer from animals to humans. In general, taking simple precautions while handling an animal or working in an animal room will prevent most zoonotic diseases. First, food and beverages should not be consumed, contacts handled, or cosmetics applied in an animal room. In addition, avoid touching your eyes, mouth, or nose while handling animals. Second, appropriate personal protective equipment (PPE) should be worn, which at minimum should include a gown, gloves, mask, hair and shoe covers. Additional PPE required is determined by the VA veterinary staff/ IACUC/ RSSC and may vary depending on the animal species and presence of hazardous materials. Third, wash your hands immediately after you are finished working with an animal. These simple steps are the most important things you can do to prevent transmitting diseases (or allergens) from animals to yourself.

If you do become ill, it is important to inform your supervisor so that an incident report can be completed by the Administrative Officer (b) (6) within 48h. You should also go immediately to the EHS (or if after hours to the VA Emergency Room) for assessment and treatment. In addition you should inform your physician that you work with animals and have experienced problems. Although you may not have contracted a zoonotic disease, it is important that your health care provider has all the facts to help in the diagnosis.

If you are pregnant or plan to become pregnant, there are additional precautions that you will need to consider when working around animals. There are hazardous agents, including biologic, chemical, and radiologic hazards, which may affect a developing child. Some of the chemical agents that may be used in an animal facility or research laboratory may be teratogens, meaning they are capable of causing birth defects. Common examples used in research facilities are certain gas anesthetics and the injectable anesthetic urethane.

There are several avenues available to obtain more information on the chemicals you and your child may be exposed to in the animal facilities or research laboratories. There are Material Safety Data Sheets (MSDS) available for you to read to determine potential risks. In addition, you should contact your obstetrician and/or an occupational medicine physician at EHS to discuss additional precautions that you should take during your pregnancy. With the information available, you and your health care provider can make an informed decision about the potential risks to your baby.

If you are immunosuppressed or have a chronic medical condition, it is important to assess the risks associated with working around animals. There are certain diseases that may not cause illness in a person with a fully functional immune system that may cause serious disease in an immunosuppressed individual. It is important to discuss the risks with your health care provider and/or an occupational medicine physician at EHS.

Animal Bites and Scratches

If you are scratched or bitten by an animal, it is important to wash the wound thoroughly with soap and water. All animals, including barrier-housed rodents, have bacteria in their mouths and under their claws, which have the capacity to cause infection if a scratch or bite is not cleaned immediately. After the wound has been cleaned, report to your supervisor to begin the documentation process (as discussed above) and go to EHS for treatment of the wound. People who are immunosuppressed should have the wound checked by their physician due to a greater chance of developing serious complications following an animal-inflicted wound. If you are injured after hours, you must go to the VA Emergency Room for documentation and treatment of the wound.

Following a scratch or bite, it is important to look for signs that may indicate that the wound has become infected, such as fever, a hot, swollen, red wound, or swollen lymph nodes. To minimize these complications, protect the wound with a bandage until it is completely healed. If you develop an infection, please consult EHS and your physician.

Although it is important to clean a wound to avoid contracting a zoonotic disease, it is even more important to prevent these types of injuries. First, it is vital that you are familiar with proper restraint and handling techniques. Animals may bite or scratch if they are not handled properly. The use of species-specific restraint devices can be a great help when you do not have an additional person to assist in handling an animal. Second, it is necessary to be knowledgeable of species-specific behaviors, including signs of aggression or fear, which may precede an injury to a handler. If you are not familiar with proper handling techniques or normal behavior patterns, please feel free to call a member of the veterinary staff (b) (6) for further training. Third, you should wear appropriate protective clothing to avoid injuries, which may include reinforced rubber, cloth, or leather gloves, depending on the species to be handled.

Allergies to Animals

Although allergies are not considered a zoonotic disease, they are one of the most important health conditions that may severely impair one's ability to work around animals. It has been reported that approximately 30% of individuals who work with laboratory animals, especially rodents and rabbits, will develop allergies. Of these, one-third may develop a chronic respiratory disease, such as asthma. Anyone who already has allergies to animals may have an even greater risk of developing allergies to laboratory animals.

People may develop allergies to any type of animal, including rodents, where dander, urine, or saliva contains substances that cause allergies. These allergens are present on dust particles and water droplets in the animal room, which is the reason individuals with allergies can have an allergic reaction just by being in the same room as an animal. It is important to limit exposure to allergens by wearing appropriate protective clothing including a gown, gloves, respirator mask, and even eye protection and by minimizing contact with the animals that cause problems for the sensitized person.

It is important to note that the blue dust masks available in the animal rooms at the VMU do not provide much respiratory protection from allergens. Only respirator-type masks (model N95) provide protection from animal allergens. To use a respirator mask, you must receive medical clearance and be fit tested by EHS staff. If you have allergic reactions to any of the animals housed at VMU, you should consider consulting with your physician or an occupational medicine physician at EHS about proper respiratory protection and/or treatment of animal allergies. Ignoring the problem may one day result in an inability to work with certain species due to severe allergic reactions.

If You Work With Hazardous Agents

The *JBVAMC Occupational Health Program for Individuals with Animal Contact,* also includes monitoring for hazardous material exposure. Prior to working with hazardous materials, details regarding their use, disposal and decontamination must be approved by the RSSC, where this may also includes approval for work with recombinant DNA (reviewed by the VA IBC committee) and/or radioactive materials (reviewed by the Radiation Safety committee). Information regarding the proper procedure to be used to safely work with hazardous material can be obtained from the members of these committees and consultation can also be sought from the JBVMC Industrial Hygienist (b) (6) [redacted]) or Safety Office (b) (6) [redacted] Also specific consultation must be done with the attending veterinarian to establish proper procedure that should be in place in the VMU to protect the researcher as well as the VMU staff.

References

- *Occupational Health and Safety in the Care and Use of Research Animals, 4th ed.* National Research Council, National Academy Press, 1999.
- *Zoonosis Updates*. American Veterinary Medical Association, 1998.

Appendix 7: IACUC/OB Membership Roster

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

Department of Veterans Affairs

Memorandum

Date: March 24, 2020

From: (b) (6) ACOS for Research and Development, Jesse Brown VA Medical Center (537/151), Chicago, IL 60612

Subj.: R&D IACUC Membership Roster

To: (b) (6)
Acting Director (537/00) Jesse Brown VA Medical Center, Chicago, IL 60612
Through: Chief of Staff (537/11)

1. Please accept the following membership roster of **appointments to the R&D IACUC** for the appointed (1) year term of October 1, 2019 through September 30, 2020 as noted below.

- (b) (6), as **Chairman** and voting member
- (b) (6), as **Vice-Chairman** and voting member
- (b) (6), as **Alternate Chairman** and voting member
- (b) (6) as a voting member
- (b) (6) as a voting member
- (b) (6), as voting member
- (b) (6), as a voting member
- (b) (6) as a voting member
- (b) (6), as a voting member
- (b) (6) as a voting member
- (b) (6) as a voting member
- (b) (6), as an alternate voting member
- (b) (6), as an alternate voting member
- (b) (6), DVM as an alternate voting member
- (b) (6) Ph.D., as an alternate voting member
- (b) (6) Anbazhagan, as alternate voting member
- (b) (6), as alternate voting member *(as of 4/1/2020)*

2. Non-voting and Administrative members are noted on the attached listed.

3. Should you have any questions, please do not hesitate to contact me at (b) (6).

(b) (6)

(b) (6)
ACOS for Research

R&D IACUC Membership Roster (10/1/19-9/30/20)
(b) (6), RD
Acting Director (537/00) Jesse Brown VA Medical Center, Chicago, IL 60612
Through: Chief of Staff (537/11)
March 24, 2020

Approved/Disapproved

(b) (6)

3/25/2020
Dated

Attachment

(b) (6)

R&D IACUC
Membership Roster of Appointments
Term Year October 1, 2019 – September 30, 2020

Regular Voting Members

- (b) (6) as Chairman and Scientific Voting Member
- (b) (6) as Vice-Chairman and Scientific Voting Member
- (b) (6), Veterinarian, as Alternate Chairman and Scientific Voting Members
- (b) (6) Research Safety Coordinator/Chemical Hygiene Officer, as Scientific Voting Member
- (b) (6) as Voting Member, Non-affiliated Community Rep
- (b) (6), as Scientific Voting Member
- (b) (6) as Non-Scientific Voting Member
- (b) (6), as Scientific Voting Member
- (b) (6), as Scientific Voting Member
- (b) (6), as Scientific Voting Member
- (b) (6) as Scientific Voting Member

Alternate Voting Members

- (b) (6) as Alternate Scientific Voting Member
- (b) (6) as Alternate Scientific Voting Member
- (b) (6) As Alternate Veterinarian, Scientific Voting Member
- (b) (6) as Alternate Scientific Voting Member
- (b) (6), as Alternate Scientific Voting Member
- (b) (6), as Alt Scientific Voting Member *(as of 4/1/2020)*

Non-Voting Members (Ex-Officio/Administrative)

- (b) (6), IACUC Administrator/VMU Facility Manager
- (b) (6), as Non-Voting Member, NU IACUC Liaison

Appendix 8: IACUC/OB Minutes

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

1) May 13, 2020 IACUC Minutes
2) June 10, 2020 IACUC Minutes

Jesse Brown VAMC IACUC

MEETING MINUTES

May 13, 2020

6th Floor R&D Conference Room

The meeting was called to order on May 13, 2020 at 9:30 AM and a quorum was present.

ATTENDANCE

Voting Members Present:

(b) (6)	Chair, Scientific, Called In
	Attending Veterinarian, Scientific, Called In
	Scientific, Called In
	Scientific, Called In
	Scientific, Called In
	Scientific, Called In
	Scientific, Research Safety Coordinator/Chemical Hygiene Officer, Called In, 9:40am
	Community Member, Non-Affiliated, Called In, 9:50am

Non-Voting Attendees, Staff and Guests Present:

(b) (6)	Non-Voting members, NU IACUC Liaison, Called In

Recording:

(b) (6)	IACUC Administrator, Called In

ITEMS

1 **General Announcements**

1.1 **The next scheduled IACUC Meeting is set for June 10th 2020**

2 **Conflict of Interest Declaration**

2.1 **All attending members must declare if there is a conflict of interest with any of the submissions being discussed at today's meeting. If conflict of interest needs to be declared, please indicate so on the document provided. Additionally, any member that has a COI must recuse themselves by presence from the committee vote. Those individuals that**

have conference called into the meeting must hang up and call back when vote has been finalized.

3 Review of the Ethical Decision Making Questions

3.1 **1. Do all our actions and decisions honor the veterans we serve? 2. Do we have all the important relevant facts to make the decision? 3. Have we involved those that should be part of the decision? 4. Does the decision reflect our organization?s core values- I CARE? 5. Do the likely benefits of the decision outweigh any potential harm? 6. How would this decision look outside the organization?**

4 Review of Previous Minutes

4.1 April 8, 2020 IACUC Minutes

Review Type:	Full Committee Review
Action:	Approved
Effective Date:	May 13, 2020
Vote:	Total = 6; For = 6; Opposed = 0; Abstained = 0;

Discussion and Remarks:

The April 8, 2020 IACUC minutes were approved as written.

5 Old Business

5.1 [1570004-1] Regulation of Hepatic Gene Expression and Metabolism

PI:	(b) (6)
Reference Number:	20-04
Submission Type:	New Project
Review Type:	Designated Member Review
Action:	Approved
Effective Date:	April 14, 2020
Project Status:	Active
Project Expiration:	April 14, 2023
Next Report Due:	April 13, 2021

Discussion and Remarks:

The PI made the requested clarifications and approval was secured.

(b) (6) [redacted]

5.2 **[1551732-1] The role of the short chain fatty acid receptor, FFAR2, in pancreatic beta-cell function**

PI: (b) (6) [redacted]
Reference Number: 20-05
Submission Type: New Project

Review Type: Designated Member Review
Action: Approved
Effective Date: April 18, 2020
Project Status: Active
Project Expiration: April 18, 2023
Next Report Due: April 17, 2021

Discussion and Remarks:
The PI made the requested clarifications and approval was secured.

The assigned DMR's (b) (6) [redacted]

6 **Annual Review of Protocols and Occupational Health**

6.1 **[1217094-9] Mechanisms and Regulation of Intestinal Cholesterol Transport**

PI: (b) (6) [redacted]
Reference Number: 18-06
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Approved
Effective Date: April 23, 2020
Project Status: Active
Project Expiration: May 20, 2021
Next Report Due: May 19, 2020

Discussion and Remarks:
This IACUC #18-06 Annual Continuation was presented and acknowledged at the May13th, 2020 IACUC meeting. This was administratively approved.

7 **Project Expiration Notice**

8 **Review of Modifications**

8.1 **[1311465-21] Osteoarthritis and Knee Joint Pain**

PI: (b) (6)
Reference Number: 18-13
Sponsor: VA Merit Award
Submission Type: Amendment/Modification

Review Type: Full Committee Review
Action: Modifications Required
Effective Date: May 13, 2020
Project Status: Active
Project Expiration: October 25, 2021
Next Report Due: October 25, 2020
Vote: Total = 8; For = 8; Opposed = 0; Abstained = 0;

Discussion and Remarks:

Modification request IACUC #18-13.14 to add animal use procdure to include using CT *IVIS spectrum* Imaging animals in-vivo and in-vitro. Currently awaiting the PI to submit the clarifications required to secure vet-consult approval.

The assigned DMR's were (b) (6)

9 **Review of Full Protocols**

9.1 **[1569927-1] Molecular Mechanisms of Nonalcoholic Fatty Liver Disease**

PI: (b) (6)
Reference Number: 20-06
Submission Type: New Project

Review Type: Full Committee Review
Action: Modifications Required
Effective Date: May 13, 2020
Vote: Total = 6; For = 6; Opposed = 0; Abstained = 0;

Discussion and Remarks:

After discussion the IACUC determined the following clarifications are required to secure approval:

Appendix 3 item 10b - PI should indicate how (the method) the isoflurane is scavenged to decrease staff exposure.

The assigned DMR's (b) (6)

10 **Semi-Annual Self Review/Resolution of Program or Facilities**

11 **Just in Time: Comparison of Grants to Protocol**

12 **Secondary Vet-Review**

13 **Administrative Reports/ VMU Team Reports**

13.1 **Update on the SOW ongoing re-heat replacement valves**

Review Type:	Full Committee Review
Action:	Acknowledged
Effective Date:	May 13, 2020

13.2 **2020 AAALAC Program Description due by August 1, 2020**

Review Type:	Full Committee Review
Action:	Acknowledged
Effective Date:	May 13, 2020

13.3 **SOP #30 Pyxis draft revision**

Review Type:	Full Committee Review
Action:	Information Required
Effective Date:	May 13, 2020

14 **Pharmacy Administrative/ Team Reports**

15 **Educational Material**

16 **Ethical Issues**

The meeting adjourned on May 13, 2020 at 10:10 AM.

(b) (6)

[redacted]

Jesse Brown VAMC IACUC

MEETING MINUTES

June 10, 2020

6th Floor R&D Conference Room

The meeting was called to order on June 10, 2020 at 9:30 AM and a quorum was present.

ATTENDANCE

Voting Members Present:

(b) (6)	Chair, Via Phone, Scientific
	Attending Veterinarian, Scientific, Via Phone
	Vice-Chair, Scientific, Via Phone
	Scientific, Research Safety Coordinator/Chemical Hygiene Officer, Via Phone
	Community Member, Non-Affiliated, Via Phone
	Scientific, Via Phone
	Scientific, Via Phone
	Scientific, Via Phone
	Scientific, Via Phone
	Scientific, Via Phone

Non-Voting Attendees, Staff and Guests Present:

(b) (6)	Non-Voting members, NU IACUC Liaison, Via Phone

Recording:

(b) (6)	IACUC Administrator, Via Phone

ITEMS

1 **General Announcements**

1.1 **The next scheduled IACUC Meeting is set for July 08, 2020**

2 **Conflict of Interest Declaration**

2.1 **All attending members must declare if there is a conflict of interest with any of the submissions being discussed at today's meeting. If conflict of interest needs to be declared,**

please indicate so on the document provided. Additionally, any member that has a COI must recuse themselves by presence from the committee vote. Those individuals that have conference called into the meeting must hang up and call back when vote has been finalized.

3 **Review of the Ethical Decision Making Questions**

3.1 **1. Do all our actions and decisions honor the veterans we serve? 2. Do we have all the important relevant facts to make the decision? 3. Have we involved those that should be part of the decision? 4. Does the decision reflect our organization?s core values- I CARE? 5. Do the likely benefits of the decision outweigh any potential harm? 6. How would this decision look outside the organization?**

4 **Review of Previous Minutes**

4.1 **May 13, 2020 IACUC Minutes**

Review Type:	Full Committee Review
Action:	Approved
Effective Date:	June 10, 2020
Vote:	Total = 9; For = 9; Opposed = 0; Abstained = 0;

Discussion and Remarks:

The May 13, 2020 Minutes secured approval after minor corrections.

5 **Old Business**

5.1 **[1569927-1] Molecular Mechanisms of Nonalcoholic Fatty Liver Disease**

PI:	(b) (6)
Reference Number:	20-06
Submission Type:	New Project

Review Type:	Designated Member Review
Action:	Approved
Effective Date:	May 15, 2020
Project Status:	Active
Project Expiration:	May 15, 2023
Next Report Due:	May 14, 2021

Discussion and Remarks:

The PI made the requested clarifications and approval was secured.

Assigned DMR's (b) (6)

5.2 **[1311465-21] Osteoarthritis and Knee Joint Pain**

PI: (b) (6) [redacted]
Reference Number: 18-13
Sponsor: VA Merit Award
Submission Type: Amendment/Modification

Review Type: Designated Member Review
Action: Approved
Effective Date: June 9, 2020
Project Status: Active
Project Expiration: October 25, 2021
Next Report Due: October 25, 2020

Discussion and Remarks:

PI made the clarification needed to secure Vet consult approval.

Assigned DMR's were (b) (6) [redacted]

6 **Annual Review of Protocols and Occupational Health**

6.1 **[1337285-3] Assessing the role of metabolism in monocyte to macrophage differentiation in pulmonary fibrosis**

PI: (b) (6) [redacted]
Reference Number: 18-07
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Approved
Effective Date: May 15, 2020
Project Status: Active
Project Expiration: October 15, 2021

Discussion and Remarks:

This IACUC #18-07 Annual Continuation was presented and acknowledged at the June10th, 2020 IACUC meeting. This was administratively approved.

6.2 **[1433637-2] Targeting MNK Pathways in Pancreatic Cancer**

PI: (b) (6) [redacted]
Reference Number: 19-14
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action:	Approved
Effective Date:	June 1, 2020
Project Status:	Active
Project Expiration:	July 25, 2022
Next Report Due:	July 24, 2020

Discussion and Remarks:

This IACUC #19-14 Annual Continuation was presented and acknowledged at the June 10th, 2020 IACUC meeting. This was administratively approved.

6.3 **[1194174-13] Osteoarthritis and Knee Joint Pain**

PI:	(b) (6)
Reference Number:	18-04
Sponsor:	VA Merit Award
Submission Type:	Continuing Review/Progress Report
Review Type:	Administrative Review
Action:	Approved
Effective Date:	June 3, 2020
Project Status:	Active
Project Expiration:	April 9, 2021
Next Report Due:	April 10, 2019

Discussion and Remarks:

This IACUC #18-04 Annual Continuation was presented and acknowledged at the June10th, 2020 IACUC meeting. This was administratively approved.

7 **Project Expiration Notice**

8 **Review of Modifications**

8.1 **[1378119-11] Hormonal control of NASH development and progression**

PI:	(b) (6)
Reference Number:	19-05
Sponsor:	VA Meret BLR&D
Submission Type:	Amendment/Modification
Review Type:	Full Committee Review
Action:	Approved
Effective Date:	June 10, 2020
Project Status:	Active
Project Expiration:	February 21, 2022
Next Report Due:	February 20, 2020

Vote: Total = 9; For = 9; Opposed = 0; Abstained = 0;
Recused = 1 (b) (6))

Discussion and Remarks:

Modifcation IACUC 19-05.09 request animal use procdure and add two compounds administered via gavage, and addtional animal numbers. (b) (6) served as Vice-Chair during the voting phase. This modifcation secured approval.

9 Review of Full Protocols

9.1 [1571905-1] Tumor suppressor function of SLC26A3/DRA

PI: (b) (6)
Reference Number: 20-07
Sponsor: UIC ICR Funding
Submission Type: New Project

Review Type: Full Committee Review
Action: Modifications Required
Effective Date: June 10, 2020
Vote: Total = 8; For = 8; Opposed = 0; Abstained = 0;
Primary Reviewer: (b) (6)

Discussion and Remarks:

After discussion the IACUC determined the following clarifications are required to secure approval:

VA Addendum Form

- Item A4, strains listed do not match that in Item C or in UIC form A
- Totals shown in Item C don't match totals in UIC form, please reconcile.
- Item F4, should uncheck first box and check, "this protocol addresses the use of transgenic rodents.
- Item I, 2. Should rewrite, implies no alternative to in vitro. Should be "Search revealed that there are no in vitro/computer modeling alternatives to in vivo studies ... then give reason why...
- Item L, (b) (6), indicates closed loop training but this procedure is not in the protocol. Please review all personnel carefully and make sure the procedures listed are only those approved in the UIC protocol. Also at the end of this section it is indicated that training dates are provided, but no training dates are listed.

App 3

- Item 2 when describing AOM prep include language that is in UIC non pharm section, indicating 0.22micron filter used.
- Item 10b remove reference to DSS in narrative.

App6

- Please change endpoint narrative for both 1 and 2 to match the revised in VA addendum Item G. Should include body condition score.

The assigned DMR's are (b) (6)

9.2 **[1571877-1] Role of intestinal SREBP2 in cholesterol homeostasis**

PI: (b) (6)
Reference Number: 20-08
Submission Type: New Project

Review Type: Full Committee Review
Action: Modifications Required
Effective Date: June 10, 2020
Vote: Total = 9; For = 9; Opposed = 0; Abstained = 0;
Recused = 1 (b) (6)
Primary Reviewer: (b) (6)

Discussion and Remarks:

After discussion the IACUC determined the following clarifications are required to secure approval:

- Page 1, A-6-2: Correct the animal number that have been already used (20 mice)?
- Page 2, section B: Although the description has been already modified, it is still complex and has to be simplified using a non-technical language. In addition, it should be better described the benefits of this research for the society. Moreover, the last sentence regarding the pain and distress to the animals is not clear. Change "no scope" for "no sign of.." and incorporate that mice will be monitored. PI does not address how the benefits of this research project outweigh the pain and distress mice may experience.
- Page 4, C2a: as written looks like 7-week experiment has been done. So, what is the rationale to do it again? This section is very confusing.
- C2a: nomenclature for mice is a bit confusing. When referring to these mice please read Jax conventions for designating mice. Abbreviate wild type mice as WT instead of ISR2-/- and ISR2+/- mice as TG (het).
- C2a: Justify the experimental design. Why is it necessary to use wild type mice as controls each time. It is possible to organize the experiment in another way?
- C2a: PI refers to the ISR2 mice developing profound hepatic fibrosis and inflammation on HFHC diets. What is not clear is whether these findings are clinically significant from an animal welfare perspective. PI should clarify if animals are clinically ill.
- Page 6, C2a: the three paragraphs about the total number of mice for experiments should be moved to section C2b.
- Page 7, C2a, study 2: Include here the rationale of "7 weeks," as it has been included in the clarification letter.
- Page 13, C2b: the first sentence regarding the effect size about human Caco2 cells is not appropriate for *in vivo* NASH studies and should be removed.
- Page 13, C2b: PI should include the justification of using male mice in experiments in this section as it plays a role in the total number of animals generated for this study.

- Page 13, C2c: in this section PI should change "ACC policies" to "JBVAMC policy for tail snips".
- Page 13, C2c: For blood, explain better procedure. Prior to performing the experiment using CO2, the investigator has to contact the veterinary staff to observe during the procedure.
- Page 13, C2c: In the procedures, should include the NASH feeding and cholestyramine feeding, the valproic acid experiment (alternative sides daily injections?) and the wire bottom cages for feces collection.
- Page 16, G1: are all people on the VA occupational health program or are some on UIC? If so, modify the table.
- Page 17, H: females should be included since in the table should describe all animals used (including breeders), not only experimental animals.
- Page 17, I: Fill the procedure headers of each category table. Cat. B: breeders; Cat. C: tail snip and inappropriate genotype and sex; Cat. D: anesthesia and cardiac puncture. Moreover, Luc+/+ mice should be removed from Category D table, since these mice are not euthanized using cardiac puncture. Update the total number of that category.
- Page 18, table category D: review number of mice for WT littermates (should be 345 taking in account 315 of IRS2-/-, 1cKO+/+ and 1cKO+/+/ISR2-/-, and 30 WT for cholestyramine experiment) and ISR2+/- (should be 120). Update the total number of the category.
- Page 20, M1: the standard husbandry for mice should be indicated. Also, the wire bottom cages should be removed from the table since it is described in appendix 6.
- Page 24, U: the cardiac puncture method should be added to the table.
- Page 28, W3: missing explanation about how the number of animals has been minimized.
- Appendix 3: PBS should be added to the table 1. Add the frequency of valproic acid administration to the table 2 and explain after the table 2 how to prepare the valproic acid (sterility, pH, etc.).
- Appendix 4, item 2,a,1 and item 4: PI should change "ACC policies" to "JBVAMC policy for tail snips".
- Appendix 4, item 3a: PI should change the explanation and say "The blood has been collected immediately prior to euthanasia".
- Appendix 6, 1a: include the frequency of diet change.

The assigned DMR's (b) (6) [redacted]

10 **Semi-Annual Self Review/Resolution of Program or Facilities**

11 **Just in Time: Comparison of Grants to Protocol**

11.1 **[1572423-1] Rational Combination of MAP4K4 Inhibition and Immunotherapy in Pancreatic Cancer**

PI:	(b) (6) [redacted]
Reference Number:	20-09
Sponsor:	VA BLRD
Submission Type:	New Project
Review Type:	Full Committee Review
Action:	Modifications Required
Effective Date:	June 10, 2020

Vote: Total = 10; For = 10; Opposed = 0; Abstained = 0;

Primary Reviewer: (b) (6)

Discussion and Remarks:

After discussion the IACUC determined the following clarifications are required to secure approval:

JIT comparison:

There some differences between grant and ACORP

- Size at which treatment is started in grant (0.2-0.5 cm3) differs from that in the ACORP
- Expt 2.2) in grant, but does not appear to be in ACORP, - To define role of MAP4K4 inhibition on host immunity and generation of CD8+ T cells and effector functions. In this sub-aim, we plan to determine role of MAP4K4 inhibition on host (in KPC mice) immunity. KPC mice (2.5 months old) will be treated either with GNE-495 (3 mg/kg body weight) or saline up to 2.5 months..... To explore role of MAP4K4-in CD8+ T cell cytotoxicity, KPC mice will be first sensitized with ovalbumin (OVA) to generate memory T cells in animals and then these animals will be treated either with GNE-495 or saline..... The in vivo cytotoxic potency of CD8+ T cells from GNE-495 or saline treated mice will also be examined. First, KPC mice will be sensitized with OVA antigen for 14 days and then treated with either GNE-495 or saline for 5 weeks. In these mice, the CFSE labelled EL4 (CFSE high) and E.G7 OVA cells (CFSE low) will be injected and kept for 6 hrs. These mice, post 6 h of challenge with CFSE labelled EL4 (CFSE high) and E.G7 OVA cells (CFSE low), animals will be euthanized and lymphocytes from spleen and liver will be isolated, and EL4 as well as E.G7 OVA cells' (present is lymphocytes isolated from animals) death will analyzed by flow.
- Expt 3.2 in grant (that is similar to Expt 5 in ACORP) indicates mice will be maintained until moribund. – "thereafter mice will be treated with Isotype IgG control (100 µg/mouse/dose), 4-1BB agonistic mab (100 µg/mouse/dose) and combination of GNE-495 (3 mg/kg body weight) and 4-1BB agonistic mab (100 µg/mouse/dose) **weekly until moribund**. However, in ACORP all studies are stopped when tumor achieves 1.5cm3. If mice become moribund they need to be Cat E and justified.

Main Body

- Item B, Second paragraph not in lay language, please read question and address appropriately. The second paragraph could be simplified and moved to C2a to give context to the experiments.
- Item C1, not in lay language – Consider "In this series of studies we will be determining the importance of the MAP4K4 pathway in progression of pancreatic cancer. We predict that expression of MAP4k4 will promote cancer, while inhibition of MAP4k4 will slow or prevent cancer. We will use 3 mouse models of pancreatic cancer 1) injection of mouse pancreatic cell lines (naïve or genetically modified to alter the expression of MAP4K4 or downstream targets) into the pancreas of normal mice (orthotopic transplantation) 2) orthotopic transplantation of human pancreatic cancer cells into humanized mice (huCD34 NSG), and 3) use of the KPC transgenic mice with spontaneous formation of pancreatic tumors. We will follow tumor progression in these mouse models with and without various drug treatments.
- Item C2a - In general, this section is written like a grant with a lot of detail related to in vitro studies and post mortem analysis. This information should be removed and only discuss issue related to animal procedures.

- Simplify Expt 1-7, Provided an example, showing simplification of Expt 1 – "We test if increasing MAP4K4 will promote pancreatic cancer. Specifically, we have generated a mouse (C57Bl6 background) pancreatic cell line (KPC-22 naive-Luc) and it has been modified to express doxycycline inducible Myc-MAP4K4 (KPC-22-Luc, iMAP4KA). Both cell lines express luciferase (Luc) which will be used to monitor tumor growth *in vivo* using the IVIS system. Specifically, these cell lines will be injected into the pancreas of C57Bl6 mice (surgical orthotopic transplantation). Starting one week after transplantation and weekly thereafter the mice will be monitored by *in vivo* IVIS imaging to determine tumor size. Once tumors reach 0.1-.3 cm^3, mice within each cell line treatment will either be given doxycycline (DOX) in the drinking water or no DOX, as shown in the following table. The mice will continue to be monitored by IVIS (once a week). All groups will be euthanized when tumors in one mouse in any group reaches 1.5 cm^3 and tumor and blood, pancreas, spleen, liver, lung collected for analysis."

- Expt with Dox in drinking water (with sweetener), it lists plain water as control, but concern that not controlling for sugar, please explain. In App 3 what is the sweetener?

- There is variation in how often the IVIS will be performed in Expt 1 every 5^{th} day, in other sections indicates every week, make sure this is consistent across the protocol. It is recognized that the 3 different mouse models may have different monitoring times.

- C,2,a Please provide a brief description of the pancreatic tumor kinetics for the KPC mice,, i.e. first time KPC mice are proposed.

- 2.a Expts. 4-7 – PI should clarify what humane endpoints for KPC and CD34-NSG mice are. C,2,c – Expt. 6 change "are moribund" to "reach humane endpoints".

- For KPC mice (expt 4), lists mice required for primary cell cultures, but a justification is not provided.

- Please provide breeding scheme to generate KPC mice to help justify number required for breeders, and the number generated but not of appropriate genotype. Do you truly maintain all three lines separate or do you maintain a double floxed Kras and Trp53, then when KPC experiment mice needed cross with PDx1 (are these het or homozygous?) if het only 50% will be of appropriate genotype and therefore more mice will be generated of inappropriate genotype than listed.

- Please make clear if your lab or your collaborator will be expanding the PDX cells, if you require mice to expand, need to discuss here and include in item C2c and number of mice in Item I.

- C2b justification is for 6-10 in general but most experiments repeat so actually need justification for 20/group, 12/group or 10/group, need justification for each of these numbers. Also need justification of the number of KPC mice for in vitro studies.

- 2.b PI did not address the issue as to whether male and female mice will be used interchangeably, i.e. males and females will not be equally distributed amongst groups.

- C2c orthotopic cell transplantation (indicate procedure used in Expt 1-3), delete rationale to use ketamine/xylazine, just state it will be used. Matrigel is indicated in App3 will it be used to mix with cells? Here indicate the typical tumor growth predicted.

- C,2,c use of ketamine and xylazine anesthesia for the first orthotopic surgical procedure yet uses isoflurane in the second description. PI should clarify and if necessary reconcile.

- C2c orthotopic transplantation of PDX (indicate procedure used in Expt 7) – the way this is written it suggest multiple tumors will be tested, but in expt 7 it is a single preparation.

- C2c IVIS, start of IVIS imaging here (4weeks after transplant) does not match that in C2a Expt 1, that indicate 1 week. How much time will IVIS imaging take?
- C,2,c monitoring by palpation and IVIS - in the IVIS section the PI indicates that tumors cannot be accurately felt by palpation, yet in the PDX tumor model, that is what will be used to assess tumor development. Please reconcile.
- C2c euthanasia, include secondary method (cervical dislocation here).
- C2c description of genotyping, move description of KPC mice earlier when discussing breeding.
- C,2,c Euthanasia is conducted in (b) (6) .
- Item E personnel, clearly indicate those that are experienced with the surgical orthotopic transplantation, the term xenographs is used, but this could simply be subcutaneous injection.
- Item I, numbers may changes related to breeding scheme of KPC mice requested above.
- Item I PI should include the PDX expansion animals/numbers in this section if this is done.
- Item J – PI should refer the reader to item T to ensure humane endpoint congruence between the two sections.
- Item N – Check "Housing in non-VA facilities" box
- Item Q Not clear what procedures are being performed in (b) (6)
- Item T As part of the endpoint criteria the PI should indicate the frequency with which the mice are observed, imaged and weighed.

Appendices

- Appendix 3 Table 1 – Please indicate the source of the tumor lines, i.e. what are the academic affiliations of the PIs listed in the table. Also, please include the PDX tumor and the source in the table.
- Appendix 3 For table2 all agents marked by an asterisk (non-pharmaceutical grade) must be addressed in the section immediately following the table.
- Appendix 3 Table 6 include the PDX tumor line
- Appendix 3 Table 10a – note UIC animal facility staff should be changed to "lab research staff".
- Appendix 3 Table 1 and 2 "sweetener" please indicate what it is. Include in Table 2.
- Appendix 3 if isoflurane is not used (see above) make sure to remove from this App and all reference to.
- Appendix 3, item 6 table middle column indicates tumor 2 cm3, but endpoint criteria does not allow tumors to get that big, so indicate, " studies will be terminated when tumors reach 1.5 cm3, a size that does not cause major pain or distress"
- Appendix 5 should be re-written to include 3 surgical procedures: 1) orthotopic injection into mouse pancreas; 2) orthotopic placement of pancreatic tumor fragments on pancreas, and 3) placement of PDX tumor pieces in the flank on animals used to expand the tumor for

placement in surgery 2 above. PI needs to address these 3 surgeries throughout the section/ appendix.

- Appendix 5 Item 2 PI should clarify the type of anesthesia used for the two pancreatic surgeries. Why different when the surgical procedure is basically the same. For surgery number two, PI should break up the description into two separate surgical procedures, i.e. the flank surgery and the fragment implantation surgery onto the spleen.
- Appendix 5 Item 7 c – PI must administer analgesia post-surgery.
- Appendix 5 item 5,b – in this section PI refers to use of ketamine xyalzine for both surgeries. PI should reconcile the anesthetic regimens to be used for the two pancreatic surgical procedures throughout the entire protocol.
- Appendix 5 Item 7 c – PI must administer analgesia post-surgery.
- Appendix 5 item 7,e,1 indicate that mice will be observed until they are able to maintain sternal recumbncy for all surgical procedures.

The assigned DMR's (b) (6) [redacted]

12 **Secondary Vet-Review**

13 **Administrative Reports/ VMU Team Reports**

13.1 **SOP #30 Pyxis draft revision**

Review Type:	Full Committee Review
Action:	Approved
Effective Date:	June 10, 2020
Vote:	Total = 10; For = 10; Opposed = 0; Abstained = 0;

14 **Pharmacy Administrative/ Team Reports**

15 **Educational Material**

16 **Ethical Issues**

The meeting adjourned on June 10, 2020 at 11:00 AM.

(b) (6) [redacted]

Appendix 9: IACUC/OB Protocol Form

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

1) ACORP Forms
    a. ACORP Main Body
    b. ACORP Appendix 1
    c. ACORP Appendix 2
    d. ACORP Appendix 3
    e. ACORP Appendix 4
    f. ACORP Appendix 5
    g. ACORP Appendix 6
    h. ACORP Appendix 7
    i. ACORP Appendix 8
    j. ACORP Appendix 9
2) Addendum for Animal Care and Use Protocols Submitted on UIC Forms
3) IACUC Modification Form
4) IACUC Annual Continuation Form
5) IACUC Protocol Reviewer Form
6) Veterinary Consultation Review Form
7) Veterinary Consultation Review Form for VA Addendum

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Main Body
VERSION 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)▶

2. VA Station Name (City) and 3-Digit Station Number▶

3. Protocol Title▶

4. Animal Species covered by this ACORP▶

5. Funding Source(s). Check each source that applies:

   ▶( ) Department of Veterans Affairs.
   ▶( ) US Public Health Service (e.g. NIH).
   ▶( ) Private or Charitable Foundation -- Identify the Foundation:
   ▶( ) University Intramural Funds – Identify the University and Funding Component:
   ▶( ) Private Company – Identify the Company:
   ▶( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

   a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

      (1) Title of project▶

      (2) If approved by the R&D Committee, give the date of approval▶

   b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

      (1) Identify the studies described in the previously approved ACORP that have already been completed
      ▶

      (2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
      ▶

      (3) Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.
      ▶

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ▶
(2) IACUC approval number of other protocol ▶
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ▶

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

▶( ) Research
▶( ) Teaching or Training
▶( ) Testing
▶( ) Breeding and colony management only; not for any specific research project
▶( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
▶( ) Other. Please specify▶

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
▶

C. **Experimental Design.**

1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
▶

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
▶

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
▶

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

D. **Species.** Justify the choice of species for this protocol.
▶

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name▶

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Name of Individual	Working with the VA IACUC	ORD web-based species specific course (Identify the species)	Any other training required locally (Identify the training)

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
▶

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	
	( )	( )	( )	
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

▶ ( ) Yes. Describe them ▶

▶ ( ) No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

Description (include the species and any other special features not shown elsewhere in this table)	Gender	Age/Size on Receipt	Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony)	Health Status

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

Procedures▶						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

J. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category D procedures.

▶ ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category E procedures

▶ ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.
▶

Veterinary Care and Husbandry

L. **Veterinary Support**.

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

   Name▶
   Institutional affiliation▶
   email contact▶

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted▶
   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ▶

M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
▶

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
▶

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.
▶

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

▶ ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
▶

▶ ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.

▶ .

▶ ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.

▶

▶ ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

▶ ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )
		( )	( )
		( )	( )

▶ ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

▶ ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

▶ ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

▶ ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".

▶ ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas?	
	Yes	No		Yes – describe method of discreet transport	No
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE Euthanasia		
		Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production")	Collected as Part of a Surgical Procedure (Appendix 5, "Surgery")	Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection")
	( )	( )	( )	( )
	( )	( )	( )	( )
	( )	( )	( )	( )

S. **Surgery.** Does this protocol include any surgical procedure(s)?

▶ ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

▶ ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

U. **Termination or removal from the protocol**. Complete each of the following that applies:

▶ ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

▶ ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death▶ Method for verifying death▶ Secondary physical method▶		( )	( )	( )
( )	Anesthetic overdose Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Decapitation under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )

( )	Exsanguination under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
   ▶

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
   ▶

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

   b. Describe how the PI's staff should be contacted.
      ▶ ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)
      Name▶
      Contact Information▶

      ▶ ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	SOP (title or ID number)*	Other Items in this ACORP -- specify the Item letter(s)	Appendix 6
		Items:	( )**
		Items:	( )**
		Items:	( )**
		Items:	( )**

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.
   ▶

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years	Potentially painful or	Key words and/or search strategy used	Indicate which mandate each search addressed

		covered by the search	distressing procedures addressed		Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
   ▶

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
   ▶

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
   ▶

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
   ▶

X. **Other Regulatory Considerations.**

1. **Controlled drugs.**

   a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Pharmacy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.
▶

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

▶ ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

▶ ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

▶ ( ) Other. Explain▶

2. **Human patient care equipment or procedural areas**. Does this protocol involve use of any human patient care equipment or procedural areas?

▶ ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

▶ ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents**. Does this protocol involve use of any explosive agent?

▶ ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

▶ ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

▶ ( ) Appendix 1, "Additional Local Information"
▶ ( ) Appendix 2, "Antibody Production"
▶ ( ) Appendix 3, "Biosafety"
▶ ( ) Appendix 4, "Ante-mortem Specimen Collection"
▶ ( ) Appendix 5, "Surgery"
▶ ( ) Appendix 6, "Special Husbandry and Procedures"
▶ ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
▶ ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

▶ ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

Item	SOP		Approval Date
	Title	ID	
C.2.c			
M.1			
M.2			
U.4.a			
U.4.b			
V			

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

   a. **Certification by Principal Investigator(s):**

   I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

   I understand that further IACUC approval must be secured before any of the following may be implemented:

   - Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
   - Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
   - Performing any additional procedures not already described in this ACORP;
   - Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

  ▶ ( ) No minority opinions were submitted by any IACUC participant for inclusion.

  ▶ ( ) Minority opinions submitted by IACUC participants are copied here ▶

  ▶ ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages▶)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC Chair	Signature	Date

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;

   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
Name of IACUC Chair	Signature	Date

   b. **Certification by Biosafety Official.** I certify that:

   - Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";

   - The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;

   - The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

- Identification of each animal such that care for individual animals can be documented.
- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

   a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

   b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date

Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

a. **Certification by the Principal Investigator(s).**

I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of Safety/Biosafety Officer for the Facility	Signature	Date
Name of ACOS for R&D	Signature	Date

Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

ACORP Appendix 1
ADDITIONAL LOCAL INFORMATION
VERSION 4

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

ACORP APPENDIX 2
ANTIBODY PRODUCTION
VERSION 4

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) and volume (ml)				

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

   d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
   ▶

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

   ▶ ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

   ▶ ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replace-ment? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

▶ ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:
▶

▶ ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
▶

c. Will volume replacement be provided for blood that is collected?

▶ ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.
▶

▶ ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).
▶

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

▶ ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.
▶ ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
▶

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

▶ ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

▶

▶ ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
▶

c. Describe how you will make sure that the animals are dead after collection of the blood:
▶

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
▶

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

▶ ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.
▶ ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
▶

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol
▶

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.
▶

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

ACORP APPENDIX 3
BIOSAFETY
VERSION 4

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of <u>All</u> Materials Administered to Animals on this Protocol.** Complete the table below for <u>all</u> materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

Material (Identify the specific agent, device, strain, construct, isotope, etc.)	**Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	**Nature of Material**						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural Drug	Euthanasia agent
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

Material* (Identify the specific agent, device, strain, construct, isotope, etc.)	**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml)	**Diluent* or Vehicle***	**Route** of admin	**Frequency or duration** of admin	**Reason** for Administration and **Expected Effects**	Location of **Further Details** in this ACORP (specify "Main Body" or "App #", and identify the Item)	Administration Under **Anesthesia, sedation, or tranquilization** (Y/N)

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)
▶

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

   a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
   ▶

   b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.
   ▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL Number of Infectious Agent	a. ABSL Number *	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?		
			Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( )**

		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ▶
Justification for applying ABSL measures that are less protective than those recommended ▶

**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

Name of Agent that Contains Recombinant Nucleic Acid	Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*	Exempt
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress**. Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

    a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

ACORP Appendix 4
ANTEMORTEM SPECIMEN COLLECTION
VERSION 4

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ▶

b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
▶

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
▶

ACORP Appendix 5
SURGERY
VERSION 4

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple*
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
▶

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
▶

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

Name	Surgery #(s)	Role in Surgery

	(see Item 1)	Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery #(s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	(*)	( )*
			( )	( )*	( )*
			( )	( )*	( )*

*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol
▶

5. **Pre-operative protocol.**

a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery #(s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( ) --	( ) --	( ) --	( ) --
2	( ) --	( ) --	( ) --	( ) --
3	( ) --	( ) --	( ) --	( ) --
4	( ) --	( ) --	( ) --	( ) --

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

6. **Intra-operative management.**

a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				
	( )*				

* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.
▶

b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
▶

c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.

▶

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

   a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile Gown	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

   * Describe any "other" measures to be taken to maintain sterility during surgery.
   ▶

   b. For each surgery, describe the immediate post-operative support to be provided to the animals.

   Surgery 1 ▶

   Surgery 2 ▶

   Surgery 3 ▶

   Surgery 4 ▶

   c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)
1					
2					
3					
4					

   *For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:
   ▶

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

e. Post-operative monitoring. <u>After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency</u>.

(1) Immediate post-operative monitoring

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

(2) Post-operative monitoring after the immediate post-operative period

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

ACORP APPENDIX 6
SPECIAL HUSBANDRY AND PROCEDURES
VERSION 4

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditioning	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.
▶

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

Procedure Number (see Item 1)	Expected Potential Pain and/or Distress			
	No	Yes		
		Description	To Be Relieved	Not to Be Relieved
1	( )		( )[a]	( )[b]
2	( )		( )[a]	( )[b]
3	( )		( )[a]	( )[b]
4	( )		( )[a]	( )[b]

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. For each procedure for which potential pain and/or distress is expected and <u>will NOT be prevented or alleviated</u>, provide the scientific justification for this:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		
3		
4		

ACORP APPENDIX 7
USE OF PATIENT CARE EQUIPMENT AND/OR AREAS
FOR ANIMAL STUDIES
Version 4

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ▶

2. **Equipment to be Used.**

   a. Identify the equipment ▶

   b. Procedure(s) to be performed with this equipment ▶

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.
   ▶

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ▶

   b. Animal species to be studied or treated ▶

   c. Number of individual animals to be studied or treated ▶

   d. Date(s) ▶

   e. Time(s) of day ▶

   f. Procedure(s) to be performed on the animals in these areas ▶

   g. Protection and cleaning of patient care room surfaces ▶

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.
   ▶

   i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
   ▶

   j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
   ▶

   k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
   ▶

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

ACORP APPENDIX 8
USE OF EXPLOSIVE AGENT(S) WITHIN THE VMU OR IN ANIMALS
VERSION 4

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s)** ▶

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

   b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the VMU	Outside of VMU
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ▶

   d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
   ▶

   e. Period of use.
   Beginning no earlier than (date) ▶
   Ending no later than (date) ▶

   f. Animals that will be administered explosive agents:
   Species ▶

Approximate weights of individual animals ▶
Approximate number of animals ▶

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

ACORP Appendix 9
DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)*
VERSION 4

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*
▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.
▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure
▶

ADDENDUM FOR ANIMAL CARE AND USE PROTOCOLS SUBMITTED ON UIC FORMS

General Information

Animal Care and Use Protocols may be submitted to the Chicago Health System VA IACUC on forms provided by the University of Illinois at Chicago (UIC) if research is to be performed at the VA using funds administered by UIC. In such instances, the following addendum MUST BE SUBMITTED AS AN ATTACHMENT.

A. **PROTOCOL Status.** Complete items A.1.- A.8. below; then proceed to item B.

1. Name of Principal Investigator:
2. VA Station Name and Number:
3. Proposal Title:
4. Animal Species covered by this protocol (list all):
5. Funding Source. Indicate the source(s) of funds that will be used to perform these animal procedures once approved by the VA IACUC:
   - ☐ U. S. Public Health Service (e.g. NIH)
   - ☐ Private or Charitable Foundation. Identify:
   - ☐ University Departmental Funds. Identify University and Department:
   - ☐ Private Company. Identify:
   - ☐ Other. Identify:

6. Is this a new project?
   - ☐ Yes. Proceed to item 7.
   - ☐ No. Answer A.6.a.-c. below.
     - a. Indicate the status of this protocol below:
       - ☐ This is an unchanged, approved protocol intended for a new funding source.
       - ☐ This is a revised protocol with a new funding source.
       - ☐ This is a revised protocol that reflects changes or additional, new studies.
       - ☐ This protocol is submitted as a three-year (3-year) renewal.
       - ☐ Other. Please specify:
     - ☐ b. Previous protocol title:
     - ☐ c. Previous IACUC approval number:

7. Do you plan on performing the animal procedures described in this form even if you do not receive extramural PHS, NSF, or other funding?
   - ☐ Yes.
   - ☐ No.

8. Indicate the type of animal use:
   - ☐ Research.
   - ☐ Teaching or Training.
   - ☐ Testing.
   - ☐ Sentinel animal use.
   - ☐ Breeding and colony management only; no experimental procedures.
   - ☐ Other. Please specify:

B. **Occupational Safety and Health.**

1. Have all personnel listed in protocol been enrolled in the VA Occupational Health and Safety Program for those with laboratory animal contact?
   - ☐ Yes. Proceed to item B.2.
   - ☐ No. If personnel have declined to participate, are enrolled in another equivalent program, or will enroll before studies commence, so indicate here and then proceed to item B.2.

2. Are there any non-routine measures such as special vaccines or additional health screening techniques that would potentially benefit research, husbandry, or veterinary staff participating in or supporting this project? Routine measures included in the Occupational Health and Safety Program (vaccination for tetanus, rabies, and hepatitis B, and TB screening) need not be mentioned here.
   - ☐ Yes. Describe them below; then proceed to item C.
   - ☐ No. Proceed to item C.

C. Complete the tables below, assigning all requested animals by breed/strain/mutant to a USDA category of pain/distress. If you have difficulty determining the appropriate category, please contact the attending veterinarian or IACUC Chair for assistance. The same animal cannot be assigned to more than one USDA category. If several different procedures are planned, the animal should be placed in a category based on the most painful/distressful procedure.

USDA Category B: List by year the number of animals that will be bred or purchased for breeding, but not used for experiments. This includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them or participate in research studies. If numbers cannot be determined exactly, estimate as closely as possible. (Note: If tail snips are necessary for genotyping, this category is not appropriate.)

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category C: List, by year the number of animals that will undergo procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category D: List by year the number of animals that will undergo procedures involving potential pain or distress that is relieved by appropriate anesthetics, sedatives, or analgesics. Examples include major and minor surgery performed under anesthesia (survival or non-survival), tissue or organ collections prior to euthanasia, painful procedures performed under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick to effectively prevent pain and/or suffering. If an endpoint is used that involves significant pain or distress, consideration should be given to putting animals into Category E.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category E: List, by year, the number of animals that will undergo procedures in which pain or stress is NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia. Examples include studies in which animals are allowed to die without intervention (e.g. LD_{50}, mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.					
Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

TOTALS: Bring all totals for each year down, by breed/strain/mutant.					
Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

D. **Description of USDA Category D and E procedures**. Are any USDA Category D or E studies planned?

☐ No. Proceed to item E.
☐ Yes. Complete items D.1. and D.2.; then proceed to item K.

1. List and describe all category D procedures by filling out the table below. If no category D studies are proposed, enter "N/A" and proceed to item D.2. For any surgical procedures you will described elsewhere in protocol, enter only a brief description in the "Procedure" column.

Procedure	Frequency of monitoring after the procedure and how long animals will be monitored	Person(s) doing the monitoring	Analgesic, sedative, or anesthetic used, plus dose, route, and duration

2. Each year a report describing and justifying all category E procedures must be submitted by each facility to the USDA and the VA. If no category E studies are proposed, enter "N/A" and proceed to item K. Otherwise, describe each category E procedure, and justify completely why pain or distress relief cannot be provided for each procedure. Your description will be used in the USDA annual report. If animals will be allowed to experience natural death as a result of experimental procedures (e.g. infectious disease or oncology studies), or an endpoint is used that allows the animals to experience significant pain or distress, you must justify why an alternate endpoint (such as weight loss, clinical signs, tumor size, etc.) prior to death or pain or distress can not be used. If animals will undergo category D procedures as well, describe them in item D.1. above.

Animal Housing and Care

E. **Laboratory Animal Veterinary Support**. Complete items E.1-E.3, then proceed to item F.

1. Give the name of the laboratory animal veterinarian responsible for providing adequate care to the animals that will be used along with their institutional affiliation.

2. VA Policy requires that a laboratory animal veterinarian be consulted during the planning stages of any procedure involving laboratory animals, before IACUC review. Give the name of the laboratory animal veterinarian consulted during the planning of procedures involving animals. As an alternative to an actual meeting, the veterinarian may perform a pre-review of the protocol and provide comments to the PI so that the protocol may be revised prior to IACUC review.

3. Give the date of the veterinary consultation (meeting date, or date written comments were provided by the veterinarian to the PI).

F. **Husbandry.**

1. Caging needs. To help the animal care staff with caging needs, please indicate the type of caging that you will need; then go on to question F.2:
   - ☐ Biohazard or other special hazard containment caging
   - ☐ Sterile rodent microisolator caging, with filtered cage top
   - ☐ Non-sterile rodent microisolator caging, with filtered cage top
   - ☐ Standard non-rodent caging, appropriate for species
   - ☐ Other. Describe:

2. The ILAR *Guide for the Care and Use of Laboratory Animals* states that consideration should be given to housing social animals in groups whenever possible. Will social animals be housed singly?
   - ☐ Yes. Complete item F.3.
   - ☐ No. Proceed to item F.4.
   - ☐ Not Applicable; the species involved is not a social animal. Proceed to item F.4.

3. Please provide a justification for housing social animals singly; then proceed to question F.4.

4. Indicate the appropriate response below:
   - ☐ This protocol does not address the use of dogs, primates, or transgenic rodents.
   - ☐ This protocol addresses the use of dogs. Answer item 4a.
   - ☐ This protocol addresses the use of primates. Answer item 4b.
   - ☐ This protocol addresses the use of transgenic rodents. Answer item 4c.

   a. Is there any scientific justification for excluding the dogs in this study from the institutional dog exercise plan required by USDA?
      - ☐ No.
      - ☐ Yes. Provide a scientific justification for excluding the dogs.

   b. Is there any scientific justification for excluding the primates from the institutional primate psychological enrichment plan required by USDA?
      - ☐ No.
      - ☐ Yes. Provide a scientific justification below for excluding the primates.

   c. Do the transgenic rodents planned for use exhibit any characteristic clinical signs or abnormal behavior related to their genotype?
      - ☐ No.
      - ☐ Yes. Describe here:

5. Will any cannulae, acrylic implants, venous catheters, or other similar medical devices be implanted into an animal such that the device extends chronically through the skin?
   - ☐ No. Proceed to item G.

☐ Yes. Explain what wound management measures will be taken to minimize the chances of chronic infections around the device(s) where they penetrate the skin.

G. Endpoint Criteria. What specific endpoint criteria will be used for determining when sick animals, both on and off study, will be euthanatized or otherwise removed from a study? Examples of appropriate criteria that should be considered include a weight loss limit as a percentage of initial or expected body weight, allowable durations of anorexia, allowable tumor size or total tumor burden expressed as a percentage of body weight, the presence of health problems refractory to medical intervention, and severe psychological disturbances. Other criteria appropriate for the species under consideration should also be considered. When complete, proceed to item H.

H. **Special Procedures.** Are any experimental procedures or special husbandry procedures planned that are NOT described in the local standard operating procedures (SOP) manual or elsewhere in this protocol? Special procedures can include special restraint practices (including non-human primate chairing), special animal health monitoring, special diets, caging, environmental control, exercise, environmental enrichment, means of identification, use of noxious stimuli, forced exercise, or behavioral manipulation.

☐ Yes. Complete and attach Appendix 6, "Special Husbandry and Procedures;" then proceed to item I.

☐ No. Proceed to item I.

Mandatory Considerations

I. **Consideration of Alternatives and the Prevention of Unnecessary Duplication.** Complete items I.1 through I.5 below; then proceed to item I. Keep copies of computer database search results in your files to demonstrate your compliance with the law if regulatory authorities or the IACUC should choose to audit your project.

1. Investigators must consider less painful or less stressful alternatives to procedures, and provide assurance that proposed research does not unnecessarily duplicate previous work. You should perform one or more database searches to meet these mandates unless compelling justifications can be made without doing so. Complete the table below for each database search you conduct to answer items H.2 throughH.5 below. You must provide complete information in the first four columns of the table to comply with USDA Policy #12.

Name of the database (s)	Date performed	Period (years) covered by each search	Key words and/or search strategy used	Indicate below for which mandate each search was conducted by placing an "X" in the proper column			
				Alternative computer models or *in vitro* techniques (item I.2)	Alternative use of less-sentient species (item I.3)	Alternative use of less stressful model or methods, or fewer animals (item I.4)	Lack of un-necessary duplication (item I.5)

2. Could any of the animal procedures described in this protocol be replaced by computer models or *in vitro* techniques? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

3. Could a smaller, less sentient mammalian species or a non-mammalian species (e.g. poultry, fish, invertebrates) substitute for the mammals in any of the experiments planned? Indicate below

if such substitution is or is not possible and provide a narrative on how you came to your conclusion.

4. Could a different animal model or different animal procedure that involves 1) less distress, pain, or suffering, or 2) fewer animals substitute for any proposed animal model or animal procedure planned? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

5. Does the proposed research unnecessarily duplicate previous work? Indicate below if the proposed work unnecessarily duplicates previous work and provide a narrative on how you came to your conclusion.

J. **Other Regulatory Considerations**. Complete items J.1, J.2, and J.3 below; then proceed to item K.

1. **Controlled drugs.**

a. Will all drugs used in animals and classified as controlled substances by the DEA or your state drug enforcement authority be stored in a double-locked cabinet, and be accessible only to authorized personnel in accordance with DEA regulations?
- ☐ Not applicable- no controlled drugs will be used. Proceed to item J.2.
- ☐ No. Please explain here, then go to item J.1.b.:
- ☐ Yes. Complete item J.1.b.

b. List the controlled substances that will be used in vivo for this project, and include the building and room number where they will be stored.

2. Will any human patient procedural areas be used for these animal studies?
- ☐ No. Proceed to item J.3.
- ☐ Yes. Complete and attach Appendix 7, "Request to Use Patient Procedural Area;" then proceed to item I.3.

3. Will an explosive anesthetic or other explosive agent be used in any portion of these animal studies?
- ☐ No. Proceed to item K.
- ☐ Yes. Complete and attach Appendix 8, "Request to Use Explosive Agent;" then proceed to item K.

K. **Test Substances.** Will test substances be administered to animals? For the purposes of this question, test substances are defined as materials administered to animals. This includes, but is not limited to, radioisotopes, toxins, antigen, pharmacological agents, infectious agents, carcinogens or mutagens, biomaterials, prosthetic devices, and cells, tissues, or body fluids.
- ☐ No. Proceed to item Q.
- ☐ Yes. Complete and attach Appendix 3, "Test Substances;" then proceed to item L.

L. **TRAINING INFORMATION**

1. Give the names of all research staff expected to work with the animals in this study. For each person listed, describe their education, training, and experience with experimental animals in general AND describe their experience performing the exact procedures in the species described in this ACORP. This description must help IACUC members determine if all animal manipulations, including surgery, testing, and blood collection, are performed by individuals who are qualified to accomplish the procedures skillfully and humanely. A listing of academic degrees alone is not an adequate response.

2. If personnel do not have experience with the exact procedures described in this ACORP, how will they be trained, who will train them, and what are the training experiences or qualifications of the person(s) doing the training? If not applicable, enter "N/A". Once completed, proceed to item M.

M. **Certifications.**

1. **Certification by Principal Investigator(s).**

To the best of my knowledge, I certify that the information provided in this Animal Care and Use Protocol is complete and accurate. I understand that IACUC approval is valid for one year only, that approval must be renewed annually, that every third year the IACUC must perform a new review of my protocol, and that I might be required to complete a newer version of the protocol and provide additional information at the time of the triennial review. I also understand that IACUC approval must be obtained before I:

- Use additional animal species, increase the number of animals used, or increase the number of procedures performed on individual animals;
- Change procedures in any way that might increase the pain/distress category in which the animals are placed, or might otherwise be considered a significant departure from the written protocol;
- Perform additional procedures not described in this protocol;
- Allow other investigators to use these animals on other protocols, or use these animals on another of my IACUC-approved protocols.

I further certify that

- No personnel will perform any animal procedures until they have been approved by the IACUC. When new or additional personnel become involved in these studies, I will submit their qualifications, training, and experience to the IACUC and seek IACUC approval before they are involved in animal studies;
- I will ensure that all personnel are enrolled in the institutional Occupational Health and Safety Program prior to their contact with animals;
- I will provide my after-hours telephone numbers to the VMU in case of emergency.

Name of Principal Investigator(s)	Signature	Date

6. **Minority Opinions (For IACUC Use).** IACUC members must be given the opportunity to submit minority opinions on this form. Enter any written minority opinions here (or attach separate pages labeled "IACUC Minority Opinion"). If there are no minority opinions, leave this space blank.

3. **Approval Signatures.**

a. To the best of their abilities, the undersigned have evaluated the care and use of the animals described in this protocol in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals* and VA Policy, and find the procedures in this protocol to be appropriate.

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC Chair	Signature	Date

b. The VA Research and Development Committee concurs with approval of the procedures described in this protocol, and has approved the overall scientific merit of this project.

Name of R&D Committee Chair	Signature	Date

JBVAMC IACUC-SRS Modification Form
Animal Component of Research Protocol (ACORP) and/or Research Safety Protocol

PLEASE TYPE ALL ENTRIES
Hand-written and/or incomplete submissions will be returned

Use this form to submit modifications to your currently approved animal use and/or approved research safety protocol. Complete items #1-6 and then answer items #7-14 in narrative form. This modification request must be electronically submitted to irbnet.org.

1. Principal Investigator: _____ 2. Date: _____

3. Protocol Title: _____

4. Investigator's University Affiliation (UIC or NU): _____

5. Applicable ACORP Protocol #: _____ / Affiliate Protocol # _____

   Approved Species/Strains: _____

6. Applicable Safety Protocol #: _____

7. Type of Modification (check all that apply)

__personnel	
__termination of animal protocol	__termination of safety protocol
__animal species or strain	__animal numbers
__animal use procedures	__animal care procedures

__use of hazardous substances/chemicals/biohazards/recombinant DNA
(please specify) _____
__other (please specify) _____

Complete each of the following items in narrative form on a separate page.

8. For new personnel, describe their qualifications and submit a "Scope of Work" form for the individual. For personnel being removed from your protocol, list their name and indicate who will be taking over their responsibilities as described in your protocol. Additionally, all employees are to be enrolled in the Occupational Safety and Health Plan accordingly for the facility that they are located in.

9. As applicable to your animal protocol provide a copy of IACUC mandated training documentation. Note: All training must be completed prior to beginning work on protocols as well as enrollment in the Occupational Safety and Health Plan

10. As applicable to your safety protocol provide a copy of the Research Safety mandated training documentation. Specific Laboratory Training for all employees located at either the JBVAMC or its affiliates (UIC or NU) are to be provided by the Principal Investigator/Immediate Supervisor. Documentation showing the specific laboratory training is to be provided to the JBVAMC R&D Admin Office. Note: All training must be completed prior to beginning work on protocols as well as enrollment in the Occupational Safety and Health Plan.

11. If this amendment covers work conducted at an affiliate institution provide a copy of the respective affiliate institution's modification request form and the affiliate institution's approval letter for the requested modification.

12. Describe and justify any proposed changes in the use of potentially hazardous substances/chemicals/biohazards/recombinant DNA. An updated chemical inventory must be provided.

13. As applicable to your animal protocol: describe and justify any proposed changes in the animal species/strains or numbers from those listed in your approved protocol. For each species/strain, clearly indicate the increase in the total number of animals to be used per year and for all years.

14. As applicable to your animal protocol: describe and justify any proposed changes in the animal use and/or care procedures from those described in your approved protocol.

15. Describe any other proposed changes to your approved protocol.

REMINDER: **PLEASE TYPE ALL ENTRIES - Hand-written and/or incomplete submissions will be returned.**

NOTE: Written approval of this modification will be forwarded to you. The results of the subcommittee's decision/review of this modification will not be released by the coordinators beforehand. Written approval letters can be expected within three (3) working days of the committee's decision/review.

Submitted by: _____ Date: _____
Signature of Principal Investigator

For R&D Admin Use Only

IACUC Modification # ___ **Designated Reviewer # ____**

Approved ____ Clarifications Needed____(see below) Withheld _____

Highest # of animals approved on original submission: _____

Highest Pain Category as listed on original submission: ____

Comments or Conditions of Approval: _____

Approved: _____ Date: _____
Chairman JBVAMC IACUC

This Modification is now incorporated into the protocol which expires on _____

*****

R&D Safety Modification Designated Reviewer # ____
Approved ____ Clarifications Needed____(see below) Withheld _____

Comments or Conditions of Approval: _____

Approved: _____ Date: _____
Chairman JBVAMC R&D Safety

ANNUAL CONTINUATION STATUS REPORT
ANIMAL CARE AND USE SUBCOMMITTEE
Jesse Brown VA MEDICAL CENTER

FIRST REQUEST

This modification request must be electronically submitted to irbnet.org.

PI Name: _____
IACUC #: _____
Protocol Title:

_____

I hereby certify that I wish to continue the protocol for animal use referenced above. By checking each box I affirm that the following conditions are met.

1. ( ) There have been no changes in any aspects of the protocol other than previously approved modifications.

2. ( ) No unanticipated issues of animal welfare have arisen.

3. ( ) Experiments are providing usable data.

4. ( ) There have been no change(s) in personnel.

5. ( ) Current Annual Enrollment in the VA Occupational Health Program or
( ) Enrollment in affiliate institution's Occupational Health Program

If any of the above boxes are not checked, please attach an explanation and if necessary, a request for a protocol modification.

6. The VA mandates all animal researchers to complete the web-based course, **"Working with the IACUC"**, and the **Species Specific training** every three years. In the table below list the **names of all personnel** in the protocol and give the date of the most recent training. The IACUC will withhold approval of the annual continuation and on the anniversary date suspend activity on any protocol in which training was completed more than one year ago. **Please add contact information: Daytime phone numbers and after hour numbers and e-mail addresses.** Website to use for your training: www.citiprogram.org

Personnel	Date Training Completed
Phone Numbers Day and Night	e-mail addresses

7. ( ) If this protocol is Subsumed (merge with other study), please provide ACC#_____

8. ( ) If this study is completed, please submit the final report.

9. ( ) I hereby certify that I do not wish to continue the protocol for animal use referenced above. PLEASE TERMINATE THIS PROTOCOL.

_____ _____

Principal Investigator Signature Date

NOTE: Failure to return this continuation form before the anniversary date of approval will result in the termination of the approval of your protocol for animal use.

JBVAMC R&D IACUC
Protocol Review

Reviewer: **Date:** **IACUC**

Protocol title:

PI: **University Affiliation:**

Funding Source: **Type of Application:**

Location(s) for housing of animals requested in ACORP:

Protocol Status Recommendation: Clarifications are required to secure approval.

Species/Strain:

No. Animals/Category:

Analgesia/Anesthetics:

Euthanasia:

Summary:

Clarifications:

Jesse Brown VA Medical Center
Veterinary Consultation
for Use of Animals in Research, Teaching and Training

The principal investigator is required by institutional policy and the Animal Welfare Act to consult with a qualified veterinarian in the planning of studies on animals prior to application for animal use to the IACUC.

A. Basic Information

- **Date of consultation:**
- **Title of ACORP:**
- **Funding Source:**
- **Principal investigator:**
- **Animal species:**

B. Instructions: Unless indicated otherwise, the document(s) you gave me to review have been shredded or deleted from email. You should consider the comments made below in the final preparation of your ACORP. It is not necessary for me to review the revised ACORP. Instead, it is your responsibility to submit the completed ACORP, a copy of this consultation form, and other supporting materials, to the IACUC coordinator. ONLY MATERIALS RECEIVED BY THE IACUC ADMINISTRATOR BY THE SUBMISSION DEADLINE WILL BE CONSIDERED AT THE IACUC MEETING.

HIGHLIGHT ALL CHANGES MADE WITHIN THE ACORP.

C. Veterinary Consultation:

1. Procedures should avoid or minimize discomfort, distress and pain. Briefly describe or list procedures that may cause discomfort, distress, or pain.

D. Application Review

Section	Description	Comment
A	ACORP Status	
B	Relevance Description	
C.1	Experimental Design – Lay Summary	
C.2	Description of Proposed Animal Use	
C.2a	Experimental Design Summary	
C.2.b	Justify Group and Total Numbers	
C.2.c	Description of Each Procedure	
D	Justification for Species/Genotype	
E	Personnel Qualifications and Training	
F	Training to be Provided	
G1	OH&S Program Enrollment	
G2	Special OH&S Needs	
H	Source/health status of Animals	
I	Numbers Requested & Pain/distress Classification	
	Description of Category D Procedures	

K	Description of Category E Procedures	
L1	Attending Veterinarian	
L2	Consulting Veterinarian/Date of Consult	
M1	Husbandry – Caging/Socialization	
M2	Husbandry – Enrichment	
M3	Customized routine Husbandry	
M3.1	Genetically Modified Animals	
M3.2	Device Implantation	
M3.3	Special husbandry needs	
N	Housing Sites	
O	Antibody Production	
P	Biosafety	
Q	Location of Procedures	
R	Fluid, Tissue & Device Collection	
S	Surgery	
T	Endpoint Criteria	
U	Termination/Euthanasia	
V	Special Procedures	
W1	Literature Searches	
W2	Alternatives: Replacements	
W3	Alternatives: Reduction	
W4	Alternatives: Refinements	
W5	Duplication Assurance	
X1	Controlled Drugs	
X2	Human Patient Procedural Areas	
X3	Explosive Substances	
Y	Appendices	
Apx 1	Use of Non-VA Animal Facility	
Apx 2	Antibody Production	
Apx 3	Test Substances	
Apx 4	Antemortem Specimen Collection	
Apx 5	Surgery	
Apx 6	Special Husbandry & Procedures	
Apx 7	Request to Use Patient Care Area	
Apx 8	Request to Use Explosive Agent	
Apx 9	Additional Local Information	
Z	Certifications	

E. Other Points/Issues/Recommendations:

F. Counsel: An approved ACORP essentially represents a binding legal agreement between the research/training team and the IACUC (and other regulatory oversight entities). As such, it is important that persons involved in the project be familiar with, and use the procedures as described in, the IACUC-approved ACORP including any anesthetic regimen, aseptic surgical technique, analgesic agents, post-procedural monitoring and care, guidelines for physical restraint, and endpoints.

G. PHS Awarded Research: If you have sent your grant to the NIH prior to IACUC review, please be advised of the following in accordance with the "Instructions for PHS 398" (United States Department of Health and Human Services, Public Health Service, Grant Application (PHS 398), Rev. 05/2001, p. 7): "Any modifications of the Research Plan section of the application, required by the IACUC, must be submitted with the follow-up certification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up certification."

Jesse Brown VA Medical Center
Veterinary Consultation for VA Addendum
for Use of Animals in Research, Teaching and Training

The principal investigator is required by institutional policy and the Animal Welfare Act to consult with a qualified veterinarian in the planning of studies on animals prior to application for animal use to the IACUC.

A. Basic Information

- **Date of consultation:**
- **Title of ACORP:**
- **Funding Source:**
- **Principal investigator:**
- **Animal species:**

B. Instructions: Unless indicated otherwise, the document(s) you gave me to review have been shredded or deleted from email. You should consider the comments made below in the final preparation of your ACORP. It is not necessary for me to review the revised ACORP. Instead, it is your responsibility to submit the completed ACORP, a copy of this consultation form, and other supporting materials, to the IACUC coordinator. ONLY MATERIALS RECEIVED BY THE IACUC ADMINISTRATOR BY THE SUBMISSION DEADLINE WILL BE CONSIDERED AT THE IACUC MEETING.

HIGHLIGHT ALL CHANGES MADE WITHIN THE ACORP.

C. Veterinary Consultation:

1. Procedures should avoid or minimize discomfort, distress and pain. Briefly describe or list procedures that may cause discomfort, distress, or pain.

D. Application Review

Section	Description	Comment
A	ACORP Status	
B1	OH&S Program Enrollment	
B2	Special OH&S Needs	
C	Pain/distress Classification	
D1	Description of Category D Procedures	
D2	Description of Category E Procedures	
E1	Attending Veterinarian	
E2	Consulting Veterinarian	
E3	Date of Veterinary Consult	
F1	Husbandry – Caging	
F2	Husbandry – Animal Socialization	
F3	Justification for Solitary Housing	
F4	Dogs, Primates, Transgenic Rodents	
F4	Exercise Plan for Dogs	

F4b	Psychological Enrichment for NHP	
F4c	Phenotypes of Genetically-mutant Mice	
F5	Medical device implant	
G	Endpoint Criteria	
H	Special Procedures	
I1	Literature Searches	
I2	Alternatives: Replacements	
I3	Alternatives: Lower Phylogeny	
I4	Alternatives: Refinements	
I5	Duplication Assurance	
J1	Controlled Drugs	
J2	Human Patient Procedural Areas	
J3	Explosive Substances	
K	Test Substances	
L	Training Information	
M	Certifications	
N	Appendices	
Apx 1	Use of Non-VA Animal Facility	
Apx 2	Antibody Production	
Apx 3	Test Substances	
Apx 4	Antemortem Specimen Collection	
Apx 5	Surgery	
Apx 6	Special Husbandry & Procedures	
Apx 7	Request to Use Patient Care Area	
Apx 8	Request to Use Explosive Agent	
Apx 9	Additional Local Information	

E. Other Points/Issues/Recommendations:

Please provide UIC letter of approval

F. Counsel: An approved ACORP essentially represents a binding legal agreement between the research/training team and the IACUC (and other regulatory oversight entities). As such, it is important that persons involved in the project be familiar with, and use the procedures as described in, the IACUC-approved ACORP including any anesthetic regimen, aseptic surgical technique, analgesic agents, post-procedural monitoring and care, guidelines for physical restraint, and endpoints.

G. PHS Awarded Research: If you have sent your grant to the NIH prior to IACUC review, please be advised of the following in accordance with the "Instructions for PHS 398" (United States Department of Health and Human Services, Public Health Service, Grant Application (PHS 398), Rev. 05/2001, p. 7): "Any modifications of the Research Plan section of the application, required by the IACUC, must be submitted with the follow-up certification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up certification."

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.

VA Semi Annual Evaluation, Program and Facility Review, February 5, 2020

Jesse Brown VA Medical Center
Station Number:**537**
City, State:**Chicago IL, 60612**
February 05, 2020

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to provide humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus in Section A (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months, and a new Inspection of the Facilities be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "►" symbols indicate **required** information:

►Date(s) of the most recent previous Review of the Program: **July 31, 2019**
►Date(s) on which this Review of the Program was conducted: **February 05, 2020**
Names of voting IACUC members who participated in the Program Review:
(The Program Review team must include a minimum of two voting members of the IACUC. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b) (6)	Attending Veterinarian	02-05-2020
	Chair	02-05-2020
	Scientific	02-05-2020

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation
(b) (6)	Animal Tech	02-05-2020

Jesse Brown VA Medical Center
Station Number:**537**
City, State:**Chicago IL, 60612**
February 05, 2020

(b) (6) [redacted]	Animal Tech	02-05-2020
(b) (6) [redacted]	IACUC Administrator	02-05-2020

3) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

N/A = Not Applicable
A = Acceptable
D= Departures, Approved by the IACUC
M = Minor Deficiency
S = Significant Deficiency

[NOTE: The items listed are only reminders of the matters to be evaluated – the wording in this checklist is not to be interpreted as altering the regulatory requirements in any way. For specifics about the regulatory requirements, the references provided in square brackets after the items must be consulted:
"1200.01" refers to the VHA Handbook 1200.01, Research and Development (R&D) Committee,
"1200.07" refers to the "VHA Handbook 1200.07, Use of Animals in Research,
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011]

4) For each item marked "M" (minor deficiency) or "S" (significant deficiency) here (Part 1, Section A), provide details in Part 2 of this form. For each item marked "D" (departure, approved), document in Part 2 the date of the IACUC meeting at which the departure was reviewed and approved. *[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3) 9 CFR (2.31 (c)(3)); and Guide (p. 9].*

5) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡- denotes a new "must" item

† - denotes a new "should" item

I. Institutional Policies and Responsibilities

		N/A	_A_	_D_	_M_	_S_
item	**A. Shared Responsibilities**					

† 100	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* **►UIC: veterinary support contract#** (b) (6) **(effective date 08-01-2019 through 07-31-2024), UIC/JBVAMC IACUC (effective date 07-07-2014) NU: MOU (effective date 08-25-2013), IACUC agreement between RUSH and the Jesse Brown VA Medical Center (effective date 03-08-2017)**		X			
	B. General IACUC Function					
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a); 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152 ✣	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154 †	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			
155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.f)]*		X			
156 †	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-.8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3)]*		X			
159	The research office must provide packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			
160	IACUC minutes must be written and published within 3 weeks of the meeting date. *[1200.07 (8)h(1))]*		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8f(2));PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d)]*		X			

163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8,f(2)(e))]*		X			
164 ‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D - 1.k(2)); 9 CFR (2.31(d)(1)(iv)(B);, Guide (p.5)]*		X			
165 ‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			
166	The IACUC must confirm approval by the SRS, the IBC, and/or the Radiation Safety Officer, as applicable, before approving any protocol involving use of hazardous agents in animal research. *[1200.07 (Appendix C-.8.c(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*		X			
168 †	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*		X			
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5)]*		X			
170	IACUC approval of each protocol expires on or before the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e. tumors, infectious disease, vaccine challenges, trauma, etc) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*		X			
173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*		X			
174 ‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*	X				
175	Toe-clipping is approved by the IACUC only used when no other alternative exists; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*		X			

176 ‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30]*		X			
	C. Semiannual Evaluations of the Animal Care and Use Program					
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B.1); 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B); 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8.f (1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8.f(1)(e)); PHS (IV.B); 9 CFR (2.31(c)(5); Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8.k(3))]*		X			
	D. Standard Operating Procedures (SOPs)					
250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ▶Date of latest review: **Review at the September 11, 2019 IACUC meeting**		X			
	E. Addressing Concerns about Animal Welfare					
300 ‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			
302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)j; 9 CFR (2.31(c)(8) and 2.31(d)(6))]*		X			

303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
305	Within 5 business days (*ORO requirement)* of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.i)]*		X			
	F. Reporting to Oversight Entities					
350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ▶Date of most recent submission: **November 25, 2019**		X			
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ▶Name of the Institution that holds the PHS Assurance: **Jesse Brown VA Medical Center** ▶Effective date of most recent approved Assurance: **January 31, 2017**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ▶Date of most recent submission: **January 31, 2020**		X			
353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.e)]* ▶Name of the Institution that holds the accreditation: **Jesse Brown VA Medical Center**		X			
354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200.07 (8.l(2)(b))]* ▶Date of most recent submission: **January 29, 2020**		X			
355	The VA Veterinary Medical Unit (VMU) annual report, which includes mice and rats, was submitted online by January 15 within the past year. *[1200.07 (8.l(4))]*		X			

356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200.07 (Appendix E-2. c); 9CFR2.35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(h));9CFR2.35(f); PHS (IV.E)]*		X			
	G. Personnel Qualifications and Training					
400 ‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)).; PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			
401 ‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(viii); Guide (p. 15 & 115)]*		X			
402 ‡	All personnel are documented as being appropriately trained for their positions, and participating annually in formal and/or on-the-job continuing education. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]* Note:*The VA provides opportunities and resources for training of all personnel and regular professional development and continuing education of the professional staff (as by participation in organizations for laboratory animal science professionals and their meetings).		X			
403 †	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			
	H. Occupational Health and Safety					
	Occupational Health and Safety Program (OHSP)					
450 ‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			

451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment** – The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			
453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
	The OHSP – Facilities and Procedures					
454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			
455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
	The OSHP – Personal Hygiene					
457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-22)]*		X			
	The OHSP – Medical Evaluation and Preventive Medicine for Personnel					

459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the VMU and for beginning work with animals. *[1200.07(Appendix C-4(2)(c))]*		X			
462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10.f(2)); Guide (p. 23)]*		X			
464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465 ✣	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466 ✣	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

II. Physical Plant

		N/A	_A_	_D_	_M_	_S_
	A. General					
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes. *[Guide (p. 133-136)]*				X	
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

III. Operations Related to Animal Environment, Housing, and Management

		N/A	_A_	_D_	_M_	_S_
	A. Physical Environment					
	Temperature, Humidity, and Ventilation					
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))]*. ▶Date of latest test: **February 05, 2020**				X	
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]* **Project in placed for FY2020**				X	
	Noise					

522	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*		X			
	B. Husbandry					
	General					
600 ‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 14)]*		X			
	Population Management					
601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
	Behavioral Management					
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60;63)]*		X			
603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51, 63-65)]*		X			
604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*		X			
	C. Animal Procurement and Transportation					
650 ‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)); Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652 ‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107); 9 CFR (Part 3, Standards)]*		X			
	D. Preventive Medicine					

700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			
701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			
	E. Waste Disposal					
750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p. 73-74)]*		X			
	F. Pest Control					
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
	G. Medical Supplies					
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200. 07 (7.m)]*		X			
851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			
	H. Emergency, After Hours, Weekend, and Holiday Animal Care					
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p, 74); 9 CFR (2.33(b))]*		X			
902 ‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			

903 †	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the VMU supervisor) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

		N/A	_A_	_D_	_M_	_S_
	A. Role of the Veterinarians					
950 ‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952 †	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg. 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			
953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14);USDA-APHIS Policy #3]*		X			
954 ‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123); 9 CFR (2.33(b))]*		X			
955 ‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			
	B. Surgery					

1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*		X			
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*		X			
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*		X			
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*		X			
1004	Presurgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p.116)]*		X			
1005	For nonsurvival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*		X			
	C. Pain, Analgesia, and Anesthesia					
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡	Procedures are in place to assure antinoception before surgery begins. *[Guide, p 122)]*		X			
1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*		X			
1053 ‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			
	D. Euthanasia					
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(xi))]*		X			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124])*		X			

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus in Section B (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note:. Federal regulations require that a new Review of the Program be completed every 6 months, and a new Inspection of the Facilities be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "►" symbols indicate required information:

►Date(s) of the most recent previous Inspection of the Facilities: **July 31, 2019**
►Date(s) on which this Inspection of the Facilities was conducted: **February 05, 2020**

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b) (6) [redacted]	Attending Veterinarian	02-05-2020
	Chair	02-05-2020
	Scientific	02-05-2020

Non-IACUC members who participated in the Facility Inspection:

Name	Title	Date(s) of Participation

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(b) (6) [redacted]		Animal Tech	02-05-2020
		Animal Tech	02-05-2020
		IACUC Administrator	02-05-2020

3) The IACUC must inspect semi-annually all units of the animal care and use program, including the following:

all areas within the VA animal facilities;
all spaces outside the VA animal facilities where animals are housed for > 12 hours;
any areas where any procedure is performed on animals.

Identify each unit subject to inspection (press Tab in bottom right cell to add rows to the table):

Location (name of site, building name and room number, etc.)	**Type of Space** (e.g., VMU, satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., VMU Supervisor, PI) **of Responsible Individual**
(b) (6)	Necropsy and Harvest Tissue	(b) (6) [redacted]
(b) (6)	Harvest Tissue	

4) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

N/A = Not Applicable
A = Acceptable
D = Departure, approved by the IACUC
M = Minor Deficiency
S = Significant Deficiency
0 = no opportunity to observe during this inspection

The last line of each section of the checklist is designated "Other Observations", for documentation of relevant observations that are not directly addressed by the checklist items.

[NOTE: References to further information about each of the items to be considered in the inspection are given in square brackets after the item:
"1200.01" refers to the VHA Handbook 1200.01, Research and Development (R&D) Committee,
"1200.07" refers to the "VA Handbook 1200.07, Use of Animals in Research,
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011]

‡ identifies each item that reflects a "must" statement found in the 8th edition of the *Guide*
† identifies each item that reflects a "should" statement found in the 8th edition of the *Guide*

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5) For each item marked "M" (minor deficiency) or "S" (significant deficiency) here (Part 1, Section B), provide details in Part 2 of this form. For each item marked "D" (departure, approved), document in Part 2 the date of the IACUC meeting at which the departure was reviewed and approved. *[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3); 9 CFR (2.31 (c)(3)); Guide (p. 9)]*

I. Implementation of Institutional Policies

item		N/A	A	D	M	S	0
A. Performance of Work According to Protocol							
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				
1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*		X				
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.		X				
1153	Routine husbandry tasks observed are being performed according to documented SOPs.				X		
B. Addressing Concerns about Animal Welfare							
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[Guide (p. 24)]*		X				
C. Occupational Health and Safety							
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8.h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				
1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) ;Guide (p. 20-22)]*		X				

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1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(l)); Guide (p. 20-22; 148-149)]*		X				
	D. Other observations:						
1300							

II. Physical Plant

		N/A	A	D	M	S	0
	A. General						
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138); 9 CFR (Part 3, Standards)]*		X				
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*		X				
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139); 9 CFR (Part 3, Standards)]*				X		
1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				
	Heating, Ventilation, and Air-Conditioning (HVAC) System						
1355	Posted logs show that temperature, humidity, and air pressure differentials are maintained within recommended ranges throughout the facility. *[Guide (p. 43-47)]*		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]* **Project in place for FY2020**				X		
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
	Power & Lighting						

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1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				
1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				
1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. For example: (1) Entry doors from corridors to animal housing areas are closed when not in use. (2) Carts, racks, and other equipment are equipped with casters. (3) Noisy animals are grouped in one section of the animal facility. (4) Sound-generating equipment is selected and located to minimize disturbance to animals *[Guide (p. 49-50; 142)]*		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		X				
B. Facilities for Sanitization							
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress, HVAC capacity, clean storage, etc.) is available and meets program needs. *[Guide (p. 143)]*		X				
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*		X				
C. Storage Areas							
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*		X				

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1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality: • Feed bag stocks are rotated and used prior to expiration date or discarded. • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. *[Guide (p. 65- 67)]*				X		
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. *[Guide (p. 69)]*		X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 142)]*		X				
	D. Facilities for Aseptic Surgery						
1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*		X				
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*		X				
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20)*		X				
	E. Special Facilities ***(include barrier, aquatics laboratory study areas, procedure areas, imaging, core service facilities ,etc.)***						
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*		X				
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*		X				
1552 ‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p 147)]*	X					
1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
	F. Ancillary Areas						

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1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. [*Guide (p. 19; 136)]*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. [*Guide (p 136)]*		X				
	G. Security						
1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*		X				
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				
	H. Other Observations:						
1700							

III. Animal Environment, Housing, and Management

		N/A	_A_	_D_	_M_	_S_	_0_
	A. Physical Environment						
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*		X				
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*				X		
1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				
1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*		X				
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				
	B. Husbandry						
General							
1800	Animals are appropriately separated by species and disease status. *[Guide (p.111)]*		X				
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.		X				

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1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/ restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1.u); PHS (IV.C.1); Guide (p. 27-33)]*		X				
Housing – Primary Enclosures							
1804 †	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63;* the *Ag Guide]* **Note:** • The minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide(p.58-59)]* • The minimum floor space recommendation for a female/litter is 51in^2 ; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]* ***Trio breeding study completed, data was brought before the IACUC September, 2014***	X	X	X			
1805 ‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807 ‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3.b)]*	X					
Population Management							

1809	Animal records (e.g., cage cards) include the following information, as appropriate: (1) Source of animals (2) Strain or stock (including genotype using standard nomenclature where applicable) (3) Name and contact information for PI (4) Protocol number (5) Pertinent dates (e.g., acquisition by facility, birth) (6) Number of individuals per group, when identified in groups (7) Age or weight (8) Gender (9) Individually identifiable features (e.g., markings, tattoos, ear tags, neck chains, implanted microchips, etc.) *[Guide (p. 75-76); 9 CFR (2.35)]*		X				
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*		X				
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*		X				
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*		X				
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*		X				
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*		X				
Food							
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*		X				
Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*		X				
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818 ‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p78;86)]*	X					

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1819 ‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					
Bedding							
1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*			X			
Sanitation							
1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				
C. Animal Procurement and Transportation							
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3.a (15)); Guide (p. 107-109); 9 CFR (Part 3, Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)); Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *Guide (p.107)]*		X				
D. Preventive Medicine							
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*		X				
E. Waste Disposal							
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*		X				
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952 ‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				
1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*				X		
F. Pest Control							

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2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*		X				
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				
	G. Medical Supplies						
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*		X				
	H. Emergency, After Hours, Weekend, and Holiday Care						
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p, 74); 9 CFR (2.33(b))]*		X				
2101 ✣	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74;114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				
	I. Other Observations:						
2150							

IV. Veterinary Medical Care

		N/A	_A_	_D_	_M	_S_	_0_
	A. General						
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				
	B. Surgery						
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*		X				
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*		X				

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2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*		X				
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*		X				
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*		X				
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*		X				
2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*		X				
	C. Pain, Distress, Analgesia and Anesthesia						
2300 ‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs. *[Guide (p. 115)]*		X				
2301 ‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303 ‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*		X				
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*		X				
	D. Euthanasia						
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351 ‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				
	E. Other Observations						

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2400	Deficiencies: as noted in Part 2 1. Clean microwave cart in breakroom 2. No Vacuum in VMU facility work order #Z200206-019 3. Vacuum indicator showing abnormal warning light is on. work order #Z200305-017				X X X		

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE
PROGRAM AND FACILITIES

PART 3 – Post-Review Documentation

Instructions (The "►" symbols indicate required information):

1) Enter identifying information in the header above:
Double click in the header area.
Then enter text after each ":"
(Note: The "Date of Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities are completed.)
Double click in the document area to return to the main body of Form 1.

2) ►Enter the date of the most recent previous Semiannual Evaluation: **July 31, 2019**

3) Enter the names of all voting members of the IACUC, and identify the member who fills each required role on the committee, in the table in Section D, below. (Press "Tab" in bottom right cell to add rows to the table.)

4) Complete Sections A-F, below.

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole. The summary should:

- Note any departures from the PHS Policy, the *Guide*, the AWA, and VA Policy.
  - If there were no departures, include a statement to this effect in the report.
  - If there are departures (refer to Part II Table of Deficiencies and Departures) list the departures, the date they were reviewed and approved by the IACUC, and summarize the rationale for each departure.
- Provide an overview of programmatic and facility deficiencies (in separate paragraphs)
  - If there were no deficiencies, include a statement to this effect in the report.
  - If deficiencies were identified, indicate if they were minor and/or significant (refer to the complete list provided in Part 2 – Table of Deficiencies and Departures). Provide a brief summary of the minor deficiencies and a concise description of each significant deficiency (include the nature of the each deficiency, the impact of the deficiency, and the corrective plan approved by the IACUC).

- Comment on any patterns or trends suggested by the observations during this semiannual evaluation and also in the light of previous semiannual reports.

- Acknowledge any laudable aspects of the overall animal care and use program (i.e., related to the program, facility, or personnel).

- Provide a concluding paragraph that: (1) assesses the institution's overall compliance with applicable PHS Policy, the *Guide*, the AWA, and VA Policy; (2) provides recommendations to the IO; and (3) highlights any other pertinent information the IO should be made aware of.

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8.f(1)(d)4); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

Yes **X** No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)].* Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program?

X Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program:

Jesse Brown VA Medical Center, UIC, Northwestern

Give the date of the most recent achievement of Full Accreditation:

Jesse Brown VA Medical Center: **March 28, 2018**

UIC:

Northwestern:

_ No. If no, describe the components that are not Fully Accredited, as indicated below.

If VA animals are housed or used at an affiliate institution that is not AAALAC accredited,

Identify the affiliate:

Give the date on which the CVMO approved this arrangement:

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If VA animals are housed or used at an institution where the AAALAC accreditation status is other than Full Accreditation,

Identify the institution:

Give the current accreditation status:

Describe briefly the current status of the institution in the process of regaining full accreditation:

D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8.f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we
1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item D of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC		DATE
(b) (6)	Chairperson/Scientist	(b) (6)	3-11-2020
	Attending Veterinarian		3-11-20
	Non-affiliated (Community) Member Voting		
	Non-scientific (Lay) Member Voting		
	Research Safety Coordinator Scientific Member		3-11-20
	Interim Contact for Radiation Safety Officer Voting		
	Vice-Chairperson/Scientist		

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(b) (6)	Scientist with Animal Research Experience		
	Scientist with Animal Research Experience		
	Scientist with Animal Research Experience (alternate)		
	Scientist with Animal Research Experience		
	IACUC Administrator Non-Voting	(b) (6)	3-11-2020
	Alternate for Dr. Fortman, Attending Veterinarian		
	Scientist with Animal Research Experience (alternate)		
	NU IACUC Liason Non-Voting		
	Scientist with Animal Research Experience		
	Scientist with Animal Research Experience		

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she has reviewed it. [1200.7(8,f(1)(e))].* **Note: the Director's signature only indicates awareness of the contents of the report, and does not imply agreement with the report or satisfaction with the corrective measures proposed. <u>The report may not be altered after it has been signed by a majority of the voting IACUC membership</u>, but any disputed items may be discussed in a cover memo.**

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Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	Signature	Date
(b) (6) Medical Center Director	(b) (6)	5/8/20

F. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to (b) (6) (b) (6) (b) (6) or as an email attachment to (b) (6) and (b) (6). The original must be retained for at least three years.

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VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES

PART 2 -- Table of Deficiencies and Departures

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Last Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities were last completed. Federal regulations require that a new evaluation be completed no later than 6 months after the last evaluation.)
   Double click in the document area to return to the main body of Form 1.

2) Deficiencies carried over from the last report – copy onto this form each item that was reported on Form 2 of the last semiannual evaluation, for which the correction was not yet completed when the last report was signed
   Enter the date the deficiency was first noted in a semiannual evaluation.
   If the IACUC determines that a change in the scheduled date of correction is appropriate, ~~strike out the previously approved date and~~ add the new date below it
   Enter the actual date when the correction of the deficiency was completed. If the work is not yet complete, leave the "Actual date of completion" blank, but include in the description any relevant information about progress to date.

   Note: Any failure to adhere to the plan and schedule that result in a significant deficiency remaining uncorrected is required by USDA to be reported in writing within 15 business days by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding that activity. Therefore, if the correction date of a significant deficiency needs to be changed; the committee must review the justification for the change and approve a new correction date at a convened committee meeting prior to the original correction date.

3) Provide details for each new deficiency noted on Form 1 (Checklist), Parts A and B, of this report, entering the following:

The date the deficiency was first noted.
The Part (A or B) and Item # on Form 1 to which it applies.
When applicable indicate by location where the deficiency was noted.
A description of the specific deficiency (in sufficient detail for an outside observer to recognize when it has been corrected), a description of any underlying programmatic or systemic conditions that may have led to the deficiency, and a description of the plans both for correcting the deficiency and for addressing underlying factors so as to prevent recurrence. *[PHS (IV.B.3)]* Be sure to include the name of the individual who will be responsible for overseeing progress on the corrective action, on behalf of the IACUC. (The table will expand to accommodate the text entered.)
The severity of the deficiency (Minor [M] or Significant [S]), as indicated on Form 1.
The schedule for correction – please indicate the date by which the IACUC has determined that the deficiency should be corrected.
The actual date when the correction of the deficiency was completed (leave blank if the work is not yet complete.)

4) For departures (D) from the PHS Policy, the Guide, the AWA, and VA Policy that have been approved by the IACUC, describe the departure, including the date of the IACUC meeting at which the departure was reviewed and approved, and a summary of the grounds for granting approval for the departure. Enter this information under the "Descriptive Details" column, enter "D" in the Category column and enter "N/A" in the Date columns.

5) Press "Tab" in bottom right cell to add rows to the table.

Original Date noted	Form 1		Location	Descriptive Details	Category			Scheduled Date of Correction	Actual Date Of Correction
	Part	Item #			M	S	D		
02-05-2020	B	1153	(b) (6)	- Clean top shelf, wire lids on rack - Clean exhaust duct grate - Clean debris behind autoclave - Clean sink, need paper towels	X			02-06-2020	02-06-2020

				(b) (6) is responsible for the correction					
02-05-2020	B	1359	(b) (6)	- Clean water staining in light diffuser (b) (6) is responsible for the correction	X			This was corrected on 02-07-2020	02-07-2020
02-05-2020	B	1153	(b) (6)	- Rat cage without cage card - Clean exhaust duct grate (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020
02-05-2020	B	1953	(b) (6)	-Sharpie container full (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020
02-05-2020	B	1359	(b) (6)	-Clean light diffuser (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020
02-05-2020	B	1359	(b) (6)	-Unlabeled vial in fume hood - Sharpie container full (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020

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02-05-2020	B	1452	(b) (6)	-PI diet chow not labeled -Storage containers dirty (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020
02-05-2020	B	2400	(b) (6)	-Clean microwave cart in breakroom (b) (6) is responsible for the correction	X			This was corrected on 02-05-2020	02-05-2020
02-05-2020	B	1254	VMU (b) (6) (b) (6)	-First aid kit was expired. (b) (6) is responsible for the correction	X			This was corrected on 02-07-2020	02-07-2020
02-05-2020	B	2400	VMU Facility	- No Vacuum in VMU facility work order was placed #Z200206-019 The Vacuum Gauge is working., however the warning light is still on. work order was placed #Z200305-017 (b) (6) is responsible for the correction	X X			This was corrected on 2-26-2020 Work order still open	2-26-2020 Work order still open

02-05-2020	A	100	Update MOU between affiliates on new forms	Update MOU between affiliates on new VA MOU forms	**X**			In progress	In progress
02-05-2020	B	1804	VMU Facility	Floor space of standard mouse box (66 sq. inches east campus and 75 sq. inches west campus) is sufficient to support trio breeding. This is based upon prior practices and experience with this housing and data collected under ACC 13-229. Breeding cages are observed for overcrowding and investigators are notified when overcrowded cages are noted. Exemption approved by IACUC based upon performance standards. ***Trio breeding study completed, data was brought before the IACUC September 2014***			**X**	N/A	N/A
02-05-2020	B	1820	VMU Facility	Sentinel mice and rats are housed with dirty bedding from mice or rat cages, respectively, from within the housing room in order to monitor the microbial status of rodents and ensure biosecurity. Exemption			X	N/A	N/A

				approved as standard practice to monitor rodent colony health status. ***IACUC 16-03 Protocol Entitled: Sentinel Animal Testing Program was approved on February 10, 2016***					
02-05-2020	A	551	VMU Facility	Ongoing VMU HVAC reheat project	**X**			Estimated Competition date FY2020	
02-05-2020	A	550	VMU Facility	Due to the reheat project, Elevations in temperature in animal rooms were not acceptable. Will need to retest in March (b) (6) [redacted] is responsible for the correction	**X**			In progress	
02-05-2020	B	1751	VMU Facility	Ventilation and air quality are not adequate in animal room. (b) (6) [redacted] will need to come out to adjust animal rooms.	**X**			In progress	

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (▶Date(s) of previous evaluation) July 31, 2019

#	Was a minor (M) or significant (S) deficiency involved? If not, enter "No; if yes enter "M" or "S"	Work order (reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	M	Z190919-011	Replace light bulb in hallway	9-19-2019	9-23-2019	4
2	M	Z190909-018	Room: (b) (6) Replace light bulb.	9-09-2019	9-07-2019	3
3	M	Z190916-031	Room: Replace light bulbs in hallway from room (b) to (b)	9-16-2019	9-16-2019	0
4	M	Z190909-017	Room: (b) Replace latch on lock	9-09-2019	10-08-2019	22
5	M	Z190909-019	Room: (b) leak from ceiling	9-09-2019	11-13-2019	47
6	M	Z191008-021	Replace: light bulb in hallway	10-08-2019	10-09-2019	1
7	M	Z200206-019	No Vacuum in VMU	2-06-2020	3-20-2020	55
8	M	Z200203-015	Room: (b) Replace light bulb	2-3-2020	2-4-2020	1
9	M	Z200203-012	Room: (b) Replace light bulb	2-03-2020	2-03-2020	0
10	M	Z200204-003	Room (b) Replace light bulb	2-03-2020	2-03-2020	0
24	M	Z200204-005	Room: (b) Replace light bulb	2-03-2020	2-04-2020	1

Table 2: Work Orders Not Yet Completed - include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below. NA

#	Minor (M) or significant (S) deficiency?	Work order (reference) number	Summarize work requested	Date work order was submitted	Elapsed days from submission until _____ (enter date used to calculate elapsed days)
	M				

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
1	24	5.6
2	2	

Comments (provide any additional information relevant to the numbers of days required for completion of the work orders submitted):

Jesse Brown VA Medical Center

Jesse Brown VAMC Research & Development

820 S. Damen Avenue

Chicago, IL 60612

Institutional Animal Care and Use Committee (IACUC)

January 24, 2020 Semi – Annual Program & Facility Self-Assessment Reviews

5 % Active Animal Projects Audit Report

BY

(b) (6) [redacted]

RESEARCH COMPLIANCE OFFICER (RCO)

OFFICE OF THE DIRECTOR

Report Date: 01/24/2020

In fulfillment of VHA handbook 1200.07 revised dated 11/23/2011 "USE OF ANIMALS IN RESEARCH" Item 8 "Institutional Animal Care and Use Committee" sub-item (f) "Functions of the VA IACUC" under sub-heading: Semi-annual Program & Self – assessment Reviews sub-item (b) on page 23, the VA IACUC must perform the review and oversight functions which is required by Public Health Service (PHS) policy, the Guide (see Monitoring the Care and Use of Laboratory Animals), the Animal Welfare Act, the United States Department of Agriculture (USDA), VA Policy, and other Federal Regulations that impact IACUC function which includes Semi-annual Program and Facility Self-Assessment Reviews. As a part of the semi-annual review, IACUC must randomly review IACUC records representing at least 5 % of the total active projects (a minimum of five).

The purpose of this review is to determine if appropriate documentation of initial review, approval letter(s), annual and triennial approvals, modifications, and investigator correspondence are present in IACUC protocol record files.

Jesse Brown VAMC IACUC has less than 100 active projects. Research Compliance Officer randomly picked 05 active projects to conduct audit to meet VHA handbook 1200.07 requirements.

Compliance Audit Tool is generated according to VHA 1200.07 requirements.

Please see attached audit data spreadsheet.

Outcome of audit: No areas of concerns were identified by Research Compliance Officer during this audit.

January 24, 2020 Semi-Annual Program & Facility Self-Assessment Reviews
5 % of Total Active Projects (a minimum of 5) Random Audit Conducted
by (b) (6), Research Compliance Officer

Serial	Principal Investigator	IACUC #	Project Title	Species	P.I. Correspondence in File	Initial Review / IACUC Approval Date	1st Annual Review Approval Y/N/NA	2nd Annual Review Approval	Triennial Review Approval	Modification(s) Approval	Audit Outcome
1	(b) (6)	# 19- 31 IRB -Net ID 1511030-1	**Intestinal 5-HT Transporter: A Novel therapeutic target for GI Disorder**	Mice B= 4, C= 1952, D= 889 Total =2854	Yes	11/22/2019	NA	NA	Term Date 11/22/2022	None	No deficiency identified
2	(b) (6)	# 19-29 IRB - Net ID 1507270-1	**DISCOVERING A NOVEL THERAPY FOR RA PATIENTS**	Mice B= 20 C= 452 D= 192 Total= 984	Yes	12/20/2019	NA	NA	Term Date 12/20/2022	None	No deficiency identified
3	(b) (6)	# 19-28 IRB Net ID 1507011-1	**Role of a Novel Gut Microbial Metabolite Receptor in Colon**	Mice C=27, D = 140 Total 167	Yes	1/10/2020	NA	NA	Term Date 01/10/2023	None	No deficiency identified
4	(b) (6)	# 19-30 IRB Net ID 1497728-1	**Microbiome and intestinal barrier in ALS Therapy**	Mice C= 475 E = 980Total= 1455	Yes	1/3/2020	NA	NA	Term Date 1/3/2023	None	No deficiency identified
5	(b) (6)	# 19-26 IRB Net ID 1498231-1	**Regulation of intestinal Sodium Absorption in Health and Disease**	Mice B=18, C=230, D= 816 Total = 1064	Yes	11/22/2019	NA	NA	Term Date 11/22/2022	None	No deficiency identified

(b) (6)

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

The VMU is supplied with 100% fresh filtered air from a dedicated unit located in the mechanical space above the facility and is designed for 10-15 changes per hour. The air is heated or cooled to the desired temperature and controlled by a computerized energy management system. Animal rooms have individual thermostats and zone humidity control.

Each occupied animal room contains devices designed to measure relative humidity and ambient room temperature. Animal care technicians record daily on a record form the maximum and minimum humidity and temperature. Humidity and temperature and are also monitored by an Edstrom Pulse system and the Engineering Services computerized energy management system.

The intake and exhaust are located on opposite sides of the building and are pressure balanced to allow rooms to remain negative or positive with respect to the corridors. The supply diffusers are located in the ceiling within each animal room; exhaust ducts are equipped with washable coarse filters located near the floor.

The VMU has zonal temperature control. The central plant uses chilled water with a redundant standby chiller to cool the rooms, and it uses both steam and hot water with a redundant boiler to heat the rooms. Both are connected to backup generator power.

In case the central cooling plant fails, the VMU has a backup chiller that was replaced in June 2017. During a power outage, perimeter heating goes to full on to prevent freezing.

Evidence of changes in ventilation rates are monitored daily by listening for the sound of the supply and exhaust fans, noting abnormally increased odors, and investigating alterations in the amount of air coming from the supply diffusers. Moreover, as part of the semi-annual inspection process rooms are assessed for odors and large air differentials between animal rooms and corridors. Ventilation rates are checked by Engineering Services or a contractor, and balanced if necessary, twice a year.

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

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

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (6)	Sterilizer Room	72°F	N	NA	N	+	10.2	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	20	07-30-2020
	BSL-2 Room	72°F	Y	67°F or less and 80°F or greater	Y	-	20.7	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	44	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	9.8	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	16	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	9.9	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	13.3	07-30-2020
	Cage Washroom	72°F	N	NA	N	-	11.1	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	14.7	07-30-2020

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

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (6)	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	15.1	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	30.8	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	33.1	07-30-2020
	Bedding Room	72°F	N	NA	N	+	12	07-30-2020
	Clean Cage Storage	72°F	N	NA	N	+	12.7	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	-	14.3	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	+	9.8	07-30-2020
	Necropsy Room	72°F	Y	67°F or less and 80°F or greater	Y	-	39.8	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	-	12.3	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	11.1	07-30-2020

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

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (6)	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	14	07-30-2020
	Animal Housing Room	72°F	Y	67°F or less and 80°F or greater	Y	-	10.5	07-30-2020
	Dirty Holding Room	72°F	N	NA	N	-	11.7	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	+	51.1	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	-	10.6	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	-	9.3	07-30-2020
	Procedure Lab	72°F	Y	67°F or less and 80°F or greater	Y	-	26.6	07-30-2020
	Pyxis Room	72°F	Y	67°F or less and 80°F or greater	Y	-	13.6	07-30-2020
	Scrub Room	72°F	Y	67°F or less and 80°F or greater	Y	+	18.5	07-30-2020

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

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

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

*

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I

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

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

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

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II

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

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

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

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

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**
Mice	11.5" x 7.7 " x 5" (66 sq. in. floor space)	<10g 10, 10-15g 8, 16-25g 5, > 25g 4	Guide Eighth Edition	Polysulfone static cages with wire lids and microisolater filtered tops
Mice	11.5" x 7.7 " x 5" (66 sq. in. floor space)	1 adult male 2 adult females w/ litter (trio breeding paradigm)	Guide Eighth Edition	Polysulfone static cages with wire lids and microisolater filtered tops
Mice	11.5" x 7.7 " x 5" (66 sq. in. floor space)	<10g 10, 10-15g 8, 16-25g 5, > 25g 4	Guide Eighth Edition	Polyethylene terephthalate (PET-E) static disposable cage bottom with wire lids and microisolater filtered tops
Mice	11.5" x 7.7 " x 5" (75 sq. in. floor space)	<10g 10, 10-15g 8, 16-25g 5, > 25g 5	Guide Eighth Edition	Polysulfone static cages with wire lids and microisolater filtered tops
Rat	19" x10.5" x 8"	<100g 7, 100-200g 6, 210-300g 4, 301-400g 3, 401-500g 2, >500g 1	Guide Eighth Edition	Polysulfone static cages with wire lids and microisolater filtered tops

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 13: Primary Enclosures and Animal Space Provisions

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	Labsan 120 Detergent	Sterilized before use
Solid-bottom cages (IVC)	N/A			
Suspended wire-bottom or slotted floor cages	Mechanical washer		Labsan 120 Detergent	Metabolic cages washed immediately after use, which is approximately 24hrs
Cage lids	Mechanical washer	Weekly	Labsan 120 Detergent	Sterilized before use
Filter tops	Mechanical washer	Weekly	Labsan 120 Detergent	Sterilized before use
Cage racks and shelves	Mechanical washer	Quarterly	Labsan 120 Detergent	
Cage pans under suspended cages	N/A			
Play pens, floor pens, stalls, etc.	N/A			
Corrals for primates or outdoor paddocks for livestock	N/A			
Aquatic, amphibian, and reptile tanks and enclosures	N/A			

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Feeders	N/A			
Watering devices	Mechanical Washer	Weekly	Labsan 120 Detergent	Water bottles and sipper tubes. Sterilized before use.
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical Washer	Weekly	Labsan 120 Detergent	Water bottles and sipper tubes. Sterilized before use.
Transport cages	Mechanical Washer	After each use	Labsan 120 Detergent	Microisolator cage may be used to transport animals
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	N/A			
Euthanasia chambers	N/A			
Macro-Environment				
Animal Housing Rooms:				
Floors	Designated Squeegee or Mop	Weekly	Labsan 256 CPQ	
Walls	Low pressure sprayer	Quarterly	Labsan 256 CPQ	
Ceilings	Low pressure sprayer	Quarterly	Labsan 256 CPQ	

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)
Ducts/Pipes	None present	N/A		
Fixtures	Low pressure sprayer	Quarterly	Labsan 256 CPQ	
Corridors:				
Floors	Mop	Daily	Labsan 256 CPQ	
Walls	Not done	N/A		
Ceilings	Not done	N/A		
Ducts/Pipes	None present	N/A		
Fixtures	Not done	N/A		
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mop	Weekly	Labsan 256 CPQ	Or after each day of use
Walls	Not done	N/A		
Ceilings	Not done	N/A		
Ducts/Pipes	None present	N/A		
Fixtures	Spray and wipe down	N/A		
Implements (note whether or not shared):				
Mops	Mop heads rinsed and soaked in disinfectant	Daily	Labsan 256 CPQ	No mops are shared between rooms

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)
Mop buckets	Cage Washer	Monthly	Labsan 120 Detergent	Buckets may be shared between rooms
Aquaria nets	N/A	N/A		
Other				
Other:				
Vehicle(s)	Cages are sprayed before transporting in temperature controlled vehicle/and placed in clean low sided plastic bin.			
Other transport equipment (list)				

*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
VMU (b) (6)		Steris 5700 Rack washer	Emergency "off" pull cord (labeled) inside of washer; Emergency shut-off button on outside of unit; Emergency power box shut-off located near equipment	Guarantee 180-degree hot water rinse; temperature-sensitive tape used after 1st use of day; RODAC plates of caging tested quarterly
VMU		Steris 3700 Bottle Washer	Emergency "off" button; Emergency power box shut-off located near equipment	Guarantee 180-degree hot water rinse; temperature-sensitive tape used after 1st use of day; RODAC plates of caging tested quarterly
VMU		Getinge 733 Sterilizer	Emergency "off" button; Emergency power box shut-off located near equipment; lock-out key; instructional signage	Bacterial Spore strip indicators performed monthly
VMU		Steris 3100 Bottle Filler	Emergency power box located near equipment	N/A

[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:	VMU (b) (6)

[*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)
Rodent Holding Rooms	30-foot candle	Surface mounted, water resistant	12:12	Automatic via Edstrom PULSE monitoring system	System timer set at 15 minutes; recorded as "alarm" in PULSE monitoring system
Surgery	Not measured	Recessed, water resistant; arm-mounted, water resistant	N/A	N/A	N/A
Necropsy	Not measured	Recessed, water resistant; arm-mounted, water resistant	N/A	N/A	N/A
Cage-Washing Room	Not measured	Recessed, water proof	N/A	N/A	N/A
Procedure rooms	Not measured	Recessed, water proof	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 the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft^2 or m^2) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes

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