Animal Care and Use Program
Standard Operating Procedures
The Louis Stokes Cleveland Department of Veterans Affairs Medical Center

March 21, 2013
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## Abbreviations/Acronyms

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<th>Description</th>
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<td>AAALAC</td>
<td>Association for Assessment and Accreditation of Laboratory Animal Care</td>
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<tr>
<td>AALAS</td>
<td>American Association for Animal Laboratory Science</td>
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<tr>
<td>ABSL</td>
<td>Animal Biosafety Level</td>
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<td>ACIH</td>
<td>American Conference of Industrial Hygienists</td>
</tr>
<tr>
<td>ACLAM</td>
<td>American College of Laboratory Animal Medicine</td>
</tr>
<tr>
<td>ACORP</td>
<td>Animal Component of Research Protocol</td>
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<tr>
<td>ACOS/R</td>
<td>Associate Chief of Staff for Research</td>
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<tr>
<td>ACUP</td>
<td>Animal Care and Use Program</td>
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<tr>
<td>AO/R</td>
<td>Administrative Officer for Research</td>
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<tr>
<td>APHIS</td>
<td>Animal and Plant Health Inspection Service</td>
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<tr>
<td>ARC</td>
<td>Animal Resource Center</td>
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<tr>
<td>ARF</td>
<td>Animal Research Facility</td>
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<tr>
<td>AVMA</td>
<td>American Veterinary Medical Association</td>
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<tr>
<td>AWAR</td>
<td>Animal Welfare Act Regulations</td>
</tr>
<tr>
<td>CC</td>
<td>Cleveland Clinic</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
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<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>CHO</td>
<td>Chemical Hygiene Officer</td>
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<tr>
<td>CITI</td>
<td>Collaborative Institutional Training Initiative</td>
</tr>
<tr>
<td>CO$_2$</td>
<td>Carbon Dioxide</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
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<tr>
<td>COIC</td>
<td>Conflict of Interest Committee</td>
</tr>
<tr>
<td>COS</td>
<td>Chief of Staff</td>
</tr>
<tr>
<td>CRADO</td>
<td>Chief Research and Development Officer</td>
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<tr>
<td>CVMO</td>
<td>Chief Veterinary Medical Officer</td>
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<tr>
<td>CWRU</td>
<td>Case Western Reserve University</td>
</tr>
<tr>
<td>DACLAM</td>
<td>Diplomate, American College of Laboratory Animal Medicine</td>
</tr>
<tr>
<td>DMR</td>
<td>Designated Member Review</td>
</tr>
<tr>
<td>DOB</td>
<td>Date of Birth</td>
</tr>
<tr>
<td>DVM</td>
<td>Doctor of Veterinary Medicine</td>
</tr>
<tr>
<td>EDIM</td>
<td>Epizootic Diarrhea of Infant Mice</td>
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<tr>
<td>EMS</td>
<td>Environmental Management Service</td>
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<td>EOC</td>
<td>Environment of Care</td>
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<tr>
<td>FCA</td>
<td>Freund’s Complete Adjuvant</td>
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<td>FCR</td>
<td>Full Committee Review</td>
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<tr>
<td>FIA</td>
<td>Freund’s Incomplete Adjuvant</td>
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<tr>
<td>Foundation</td>
<td>Cleveland VA Research and Education Foundation</td>
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<tr>
<td>Guide</td>
<td>Guide for the Care and Use of Laboratory Animals</td>
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<tr>
<td>HRMS</td>
<td>Human Resources Management Services</td>
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<tr>
<td>HVAC</td>
<td>Heating, Venting and Air Conditioning</td>
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<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
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<tr>
<td>IBC</td>
<td>Institutional Biosafety Committee</td>
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<tr>
<td>IC</td>
<td>Intracranial</td>
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<tr>
<td>ID</td>
<td>Intradermal</td>
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<tr>
<td>IM</td>
<td>Intramuscular</td>
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<tr>
<td>IO</td>
<td>Institutional Official</td>
</tr>
<tr>
<td>IP</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>ISO</td>
<td>Information Security Officer</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>IT</td>
<td>Intrathecal</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
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</table>
JIT  Just in Time
LAR  Laboratory Animal Resources
LCM  Lymphocytic Choriomeningitis Virus
LSCDVAMC  Louis Stokes Cleveland Department of Veterans Affairs Medical Center
MAP  Mouse Antibody Production
MEC  Medical Executive Committee
MHV  Mouse Hepatitis Virus
MMV  Minute Virus of Mice
MNV  Mouse Norovirus
MOU  Memorandum of Understanding
MPV  Mouse Parvovirus
NIH  National Institutes of Health
NIOSH  National Institute for Occupational Safety and Health
OHSP  Occupational Health & Safety Program
OLAW  Office of Laboratory Animal Welfare
ORD  Office of Research and Development
ORO  Office of Research Oversight
OSHA  Occupational Safety and Health Administration
PAM  Post Approval Monitoring
PCR  Polymerase Chain Reaction
PH  Personnel Health
PHS  Public Health Service
PI  Principal Investigator
PPE  Personal Protective Equipment
PPM  Parts Per Million
PRIM&R  Public Responsibility in Medicine and Research
PVM  Pneumonia Virus of Mice
QIP  Quality Improvement Program
RAP  Rat Antibody Production
RCV/SDAV  Rat Coronavirus/Sialodacryoadenitis
R&D  Research and Development
R&DC  Research and Development Committee
RCA  Research Compliance Auditor
RCO  Research Compliance Officer
RCC  Research Credentialing Coordinator
Reo-3  Reovirus-3
RIRM  Research Information Resource Manager
RRRP  Request to Review Research Proposal
RSC  Research Safety Coordinator
RSC/CHO  Research Safety Coordinator/Chemical Hygiene Officer
RSO  Radiation Safety Officer
SC  Subcutaneous
Sendai  Sendai Virus
SOPs  Standard Operating Procedures
SRS  Subcommittee on Research Safety
TMEV  Theiler’s Encephalomyelitis Virus
US  United States
USDA  United States Department of Agriculture
VA  Veterans Affairs
VACO  VA Central Office
VHA  Veterans Health Administration
VMU  Veterinary Medical Unit
WOC  Without Compensation
1. Animal Care and Use Program (ACUP)

1.1 Introduction
The Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) Animal Care and Use Program (ACUP) Standard Operating Procedure (SOP) is a reference for Investigators, study staff, Animal Research Facility personnel, and Institutional Animal Care and Use Committee (IACUC) members. This SOP details the policies and procedures governing animal research and the requirements for submitting research proposals for review to the IACUC.

1.2 Mission
The LSCDVAMC recognizes the scientific and ethical responsibility for the humane care and use of animals involved in research, teaching, and testing and advises all individuals involved to maintain the highest standards of animal care and responsibility. This responsibility extends to investigators to protect animals as well as to comply with the specific requirements established and regulated by the sponsors of their research, VA policies, federal regulations, and state and local polices that govern animal care and use.

1.3 Background
Animal subjects contribute immeasurably to advancements in medical science. Most research and testing involving human patients is based on the results of animal experimentation. To provide hope for veterans suffering from diseases that currently lack cures or effective treatments, the VA actively supports the use of animals in research, teaching, and testing. However, the use of animals in VA research is a privilege granted with the understanding and expectation that such research is conducted according to the highest ethical and legal standards.

All animal care, husbandry, and animal research practices at VA animal facilities must be in accordance with applicable laws, regulations, and policy. The basic principles governing animal research in VA are found in the United States (U.S.) Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, which include the following imperatives:

- Animal experiments are undertaken only after due consideration of their relevance for human or animal health and the advancement of biological knowledge.
- The fewest number of animals needed to achieve scientific objectives is to be used.
- The least sentient species that will permit the attainment of research objectives is to be used.
- The least painful or distressful procedures needed to meet research objectives are to be used, and all reasonable measures to minimize pain and distress should be utilized.
- When planning and conducting studies, the principles of replacement, reduction, and refinement must be considered.
- Procedures that would be considered painful in a human must be considered to be painful in an animal.
- The best possible living conditions must be maintained for animals kept for research, training, or testing purposes. Animal care needs to be supervised by a veterinarian experienced in laboratory animal medicine. Housing must ensure that the general health of animals is safeguarded and that undue stress is avoided, with appropriate
attention paid to environmental factors such as temperature, ventilation, and humidity.
- Personnel must have appropriate qualifications, training, and experience when conducting procedures on animals. Opportunities for hands-on training need to be provided as needed.

1.4 Authority to Conduct Animal Research
Because the LSCDVAMC conducts animal research according to the highest ethical and regulatory standards, all animal research complies with the Health Research Extension Act (codified at 42 U.S.C. Section 289d) and the Public Health Services (PHS) Policy. The PHS Policy includes the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (prepared by the Interagency Research Animal Committee), The Guide for the Care and Use of Laboratory Animals (prepared by the National Research Council; henceforth called the Guide) and the Report of the AVMA Guidelines on Euthanasia. **NOTE: Compliance with PHS Policy is mandated by VA policy, whether or not PHS funds are accepted by an individual VA facility.**

All animal research must be covered by a PHS Assurance. By law, all animal research must comply with the Animal Welfare Act (codified at 7 U.S.C. Sections 2131-2159), the United States Department of Agriculture (USDA) AWAR (Animal Welfare Act Regulations and Standards) (Title 9 Code of Federal Regulations (CFR) Parts 1-4), and 42 CFR 73, Possession, Use, and Transfer of Select Agents and Toxins. All VA animal research involving infectious or recombinant agents must also comply with guidelines found in the latest editions of the Centers for Disease Control and Prevention (CDC)-National Institutes of Health (NIH) publication entitled “Biosafety in Biomedical and Microbiological Laboratories” and the NIH publication entitled “NIH Guidelines for Research Involving Recombinant DNA Molecules.”

1.5 Regulatory Mandate to Protect Animals in Research

1.5.1 Animal Welfare Act
The Animal Welfare Act is administered through the USDA. It regulates transportation, purchase, care and treatment of animals used in research, exhibitions and sold as pets. The Animal Welfare Act does not cover birds or laboratory rats and mice. The Animal Welfare Act addresses such issues as exercise for dogs, care of non-human primates to ensure their psychological well-being; the composition and duties of the IACUC; responsibilities of the attending veterinarian; and training of all personnel using laboratory animals in experimentation. The Act requires the IACUC to review all protocols using vertebrate animals and to conduct semiannual inspections of all animal study areas and research facilities. Oversight is provided by APHIS (Animal and Plant Health Inspection Service). The full text of the Animal Welfare Act can be accessed on-line through the USDA web site at: [http://www.nal.usda.gov/awic/legislat/awa.htm](http://www.nal.usda.gov/awic/legislat/awa.htm)

1.5.2 Public Health Service Policy (PHS or NIH Policy).
The PHS Policy requires that the LSCDVAMC file an approved “Animal Welfare Assurance Statement” with PHS in order to receive PHS funds for animal research. The “Animal Welfare Assurance Statement” commits the LSCDVAMC to comply with the guidelines as described in the “Animal Welfare Act”, the Guide and the “U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.” Oversight is provided by OLAW (Office of Laboratory Animal Welfare). Copies of the PHS
assurance, annual updates, and correspondence to and from OLAW are sent to the Chief Veterinary Medical Officer (CVMO).

The *Guide* charges users of research animals and IACUCs with the responsibility of achieving specified outcomes (e.g., animal well-being, sanitation, and occupational safety) but allows them to determine the specific methods to accomplish these goals. This is called a “performance” approach. Because the *Guide* is written in general terms, IACUCs have a key role in interpretation, oversight, and evaluation of institutional animal care and use programs. IACUCs function as self-regulating bodies. The complete text of the *Guide* can be found at: https://download.nap.edu/chapterlist.php?record_id=12910&type=pdf_chapter&free=1

1.5.3 VA Regulations, Guidelines, and Documents
VA regulations, guidelines, and documents that apply to animal research are listed under “VHA Handbook 1200.7.” These standards and regulations are based on the Animal Welfare Act and PHS policy. The entire document can be accessed at: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2464

1.6 Guiding Principles
According to the *Guide*, the guiding principles encourage:
- Design and performance of procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society.
- Use of appropriate species, quality, and number of animals.
- Avoidance or minimization of discomfort, distress, and pain in concert with sound science.
- Use of appropriate sedation, analgesia, or anesthesia.
- Establishment of experimental end points.
- Provision of appropriate animal husbandry directed and performed by qualified persons.
- Conduct experimentation on living animals only by or under the close supervision of qualified and experienced persons.

1.7 Animal Welfare Assurance
The LSCDVAMC ACUP operates under the authority of its current PHS approved Animal Welfare Assurance (A3928-01).

1.8 Accreditation of the Animal Care and Use Program
VA animal facilities and affiliates, or other animal facilities that house animals procured with VA funds, or used for VA or VA research and education corporation projects must be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). AAALAC is a non-profit organization that inspects animal facilities on a triennial cycle and reviews institutional animal care and use programs. AAALAC was established by scientific and educational organizations to ensure high standards of laboratory animal care and use. It has no federal regulatory authority but is an organization that provides monitoring to ensure institutions comply with the principles established in the *Guide* and other applicable mandates.
The LSCDVAMC has maintained full AAALAC accreditation of its animal care and use program since 1975. This accreditation is renewed after program evaluation every three years.

1.9 Institutional Authority
The LSCDVAMC ACUP operates under the authority of the medical center policy 151-001 “Research & Development Committee” and 151-003 “Protection of Animal Subjects in Research Establishing an Institutional Animal Care and Use Committee.”

1.10 Definitions
American College of Laboratory Animal Medicine (ACLAM). ACLAM is the specialty certification board for laboratory animal veterinarians, recognized by the American Veterinary Medical Association.

American Veterinary Medical Association (AVMA). AVMA is the principal professional organization for veterinarians engaged in any specialty of the practice of veterinary medicine.

Animal. The term “animal” is defined in VA Handbook 1200.7 as any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose (see PHS Policy on Humane Care and Use of Animals, Sec. III).

Animal Research. Animal research refers to any use of laboratory animals in research, testing, or training.

Animal Component of Research Protocol (ACROP). The ACORP, the official VA animal protocol form, is the set of questions that must be considered during a review of animal protocols. This form is located in appendix 3.

Animal Incident Report. The anonymous report designed to notify a designated institutional official of alleged wrongful conduct in animal research. This report is located in Appendix 7.

Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). AAALAC is the accrediting body for animal research programs recognized by VA.

Chief Executive Officer (CEO). As the highest ranking administrative official at the local VA medical center, the Director must serve as the CEO, and appoint IACUC members to the VA IACUC as required by the Animal Welfare Act (7 U.S.C. § 2143[b][1]) and the Health Research Extension Act (42 U.S.C. §289d).

Chief Research and Development Officer (CRADO). The CRADO is the VA Central Office research administrator given the authority and the responsibility for managing all human, animal, and laboratory VA research activities. Responsibilities include policy, portfolio, and budget management. NOTE: The CRADO directs the Office of Research and Development (ORD), VA Central Office.
Chief Veterinary Medical Officer (CVMO). The VA Central Office veterinarian given the primary responsibility for formulating VA animal research policy, advising senior VA administrators on animal research issues, and providing support and guidance as needed to field research personnel conducting animal research. Veterinary medical and laboratory animal concerns and issues are the purview of the CVMO.

Designated Member Review (DMR). An ancillary method of approval for protocols, annual reviews and addenda involving one or more reviewers designated by the IACUC Chair. DMR may be used when there is no call for FCR within 7 days of notification of all IACUC members of the receipt of a protocol item by the IACUC Coordinator. DMR may also be used to complete the approval of a protocol item discussed at FCR when a unanimous vote of the IACUC is obtained.

Full Committee Review (FCR). The default method of approval for all protocols, involving approval by a convened IACUC.

Institutional Animal Care and Use Committee (IACUC). The IACUC is the local committee that is legally responsible for ensuring that all animals used in activities covered by federal guidelines and regulations are cared for and used in a humane manner and that all activities are in compliance with all federal regulations and guidelines. In the VA system, the IACUC is organized administratively as a subcommittee of the Research and Development (R&D) Committee.

IACUC Chair. The voting member of the IACUC who performs the functions and responsibilities of Chairperson. This individual is appointed annually by the Medical Center Director as the Chair of the IACUC and cannot be the Veterinary Medical Officer or the non-affiliated member. This person has usually served on the LSCDVAMC IACUC for at least one year.

Institutional Official (IO). The IO is the VA official responsible for ensuring that the animal research program has the resources and support necessary to comply with all Federal regulations and guidelines that govern the use of laboratory animals. The IO is the point of contact for correspondence addressing animal care and use issues with the United States Department of Agriculture (USDA), the Public Health Service (PHS), AAALAC, VA ORD, and VA Office of Research Oversight (ORO). As mandated by VA Handbook 1200.7, the Medical Center Director must fulfill the role of IO for VA research programs except when a VA medical center does not have its own PHS Assurance, or when it is accredited by AAALAC as part of an affiliate's program. In such cases, an administrator at the affiliate institution must assume the role of the IO for PHS correspondence to comply with the PHS Policy (see Sec. II and Sec. III.G) and/or the role of IO for communication with AAALAC regarding accreditation matters.

Just-in-Time (JIT). JIT refers to the ORD review system (for VA applications involving animals) that requires proof of IACUC approval and a copy of an ACORP, only if an application has received favorable scientific review and is likely to receive funding.

Major Change. A protocol modification that deviates significantly from the original animal use protocol. Major changes may include a change in pain category; change from terminal to survival procedure; a request for an increase in the number of animals of non-USDA
regulated species that exceeds 10% of the number originally requested; addition of 1 or more animals of a USDA regulated species; change in endpoint criteria that would increase the amount of time animals may experience pain or distress; addition of previously untested or unknown test articles or substances; change in species; change in PI (Refer to the OLAW IACUC Guidebook, page 95). This form is found in Appendix 5.

**Major (Significant) Compliance Deficiency.** Any infraction that cannot be defined as a minor deficiency. A major deficiency can include, but is not limited to, unauthorized procedures and surgeries.

**Major Surgery.** Where surgical procedures penetrate and/or expose a body cavity or produce substantial impairment of physical or physiologic function.

**Memorandum of Understanding (MOU).** A memorandum detailing how research projects that are conducted at another institution using VA or VA non-profit research foundation funds are monitored, approved, and performed, in order to ensure compliance with all applicable laws and regulations. This must be approved and signed by the Institutional Officials of both institutions.

**Minor Change.** A protocol modification that cannot be defined as a major change. Minor changes may include a change in animal strain; location of non-surgical animal procedures or of rodent surgery; intra-operative procedure that does not involve hazardous agents, sedation, anesthesia, analgesia, neuromuscular blockade, or antimicrobial therapy; personnel other than PI who are already approved for equivalent procedures in another ACORP; collection of tissue after euthanasia. This form is found in Appendix 4.

**Minor (nonsignificant) compliance deficiency.** Any infraction that cannot be defined as a significant deficiency. A minor deficiency can include, but is not limited to, inadequate record keeping and unapproved minor changes in procedures.

**Minority Opinion.** A minority opinion is the dissenting opinion of one or a minority of the membership regarding a specific issue that is up for approval.

**Multiple Major Survival Surgery.** Where an individual animal subject undergoes more than one major survival surgical procedure.

**Non-Survival Surgery.** Surgery in which animals are maintained at an anesthetic plane which precludes pain and distress and in which animals are euthanized before recovery from anesthesia.

**Office of Laboratory Animal Welfare (OLAW).** OLAW is the PHS Office responsible for administering PHS Policy on Humane Care and Use of Laboratory Animals (henceforth referred to as PHS Policy).

**Office of Research Oversight (ORO).** ORO serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance regarding human subjects’ protections, animal welfare, research safety, and research misconduct.
Principal Investigator (PI). A research scientist performing animal research at LSCDVAMC or using VA or VA foundation funds to perform animal research at an institute with whom the LSCDVAMC has a Memorandum of Understanding (MOU).

Public Health Service Assurance (PHS Assurance, or Animal Welfare Assurance). PHS Assurance is the documentation submitted to the OLAW (USDA), by an institution that pledges that the institution will comply with PHS Policy.

Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). PHS policies require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted or supported by PHS (see subpar. 3m). VA policy requires compliance with PHS Policy even if PHS funds are not received.

Quorum. A majority (more than 50%) of voting members. For voting purposes, a member directly associated with a protocol with a financial conflict of interest or issue cannot be considered part of the quorum.

Rodent Surgery. Surgery performed on animals of the family Rodentia. The special surgery regulations pertain specifically to rodent surgery whether or not rodents are USDA covered species.

Survival Surgery. Surgery where animals recover consciousness following surgical procedures.

Reduction. Reduction is minimizing the number of animals needed for research, testing, or training. Reduction may include optimizing a study to utilize animals as their own controls, gathering a maximum amount of data from each animal subject (e.g., by gathering data for more than one experiment concurrently, or designing experiments to prevent the need for duplicate control groups), and using more sophisticated measuring techniques to improve precision and to reduce the sizes of the groups needed.

Refinement. Refinement is modification of experimental protocols to minimize pain or distress, whenever possible. Examples include:
- Use of less painful/distressful procedures to accomplish a research objective.
- Identifying ways to prevent or relieve pain or distress likely to be caused by experimental procedures;
- Setting the earliest possible endpoints for the research;
- Using more appropriate analgesics and anesthetics for potentially painful procedures as they become available; and
- Increasing the effectiveness of post-surgical care with new technology.

Replacement. Replacement usually refers to the use of in vitro techniques or computer simulations in place of procedures on animals. Sometimes the term is applied to the use of less sentient species, such as invertebrates, birds, and reptiles, in place of more sentient animals such as mammals.

Research. The testing of concepts by the scientific method of hypothesis formulation, systematic and recorded collection of relevant data, and interpretation of the results in
terms of the hypothesis or, more simply, a systematic investigation designed to develop or contribute to generalizable knowledge. Research and development in the VA includes the investigation and refinement of biomedical problems and hypotheses related to health and diseases.

**Research and Development (R&D) Committee.** The R&D Committee is charged with overseeing and approving all research projects at the medical center. In the VA system, committees such as the IACUC, the Subcommittee for Research Safety (SRS), and the Institutional Review Board (IRB) are organized administratively as subcommittees of the R&D Committee.

**Restraint/Immobilization.** Restraint is the use of manual, mechanical, or chemical means to limit some or all of an animal's normal movement for such purposes as examination, collection of samples, and drug administration. Typically, animals are restrained for brief periods, usually seconds or minutes, in most research applications.

**Significant compliance deficiency.** Any infraction that is or may be a threat to the health or safety of the animals. A significant deficiency may include, but is not limited to, neglect or cruelty to animals, conducting animal research outside of regulatory oversight, non-adherence to specific and previously agreed upon policies and guidelines, non-adherence to the written protocol, inadequate training of all participants involved with animal experimentation, repeated minor infractions.

**Subcommittee for Research Safety (SRS).** SRS is the subcommittee of the R&D Committee that reviews and approves the use of hazardous substances in VA research.

**United States Department of Agriculture (USDA).** USDA is charged with enforcing the Animal Welfare Act Regulations and Standards (henceforth known as USDA AWAR). The USDA Animal Care Section in the Animal and Plant Health Inspection Service is the administrative unit given the responsibility for monitoring compliance with USDA AWAR.

**Veterinary Medical Unit (VMU).** The VMU consists of the animal research facility plus the husbandry and veterinary technical personnel assigned to care for animals.

**Vice-Chair.** The voting member of the IACUC who performs the functions and responsibilities of Chairperson in his or her absence. This individual is appointed by the Medical Center Director as the Vice-Chair of the IACUC and cannot be the Veterinary Medical Officer or the non-affiliated member. This person has usually served on an IACUC for at least one year.

**1.11 Activities Covered by the ACUP**
The LSCDVAMC ACUP covers all research involving animals that is conducted completely or partially in LSCDVAMC facilities, conducted in approved off-site locations, facilities, and/or conducted by LSCDVAMC researchers, employees, or agents, while on official VA duty time. The research may be VA funded, funded from non-VA sources, or conducted without direct funding.
1.12 Types of Research Typically Covered by the ACUP
The ACUP is an essential component of the LSCDVAMC research activities. Research conducted at the LSCDVAMC is generally designed to advance health care for our veteran population and the nation.

1.13 Categories of Animals Typically Covered By the ACUP
The LSCDVAMC ACUP typically covers research involving mice, rats, cats, rabbits, and dogs.

1.14 Written Policies and Procedures
The LSCDVAMC medical center policy 151-003 “Protection of Animal Subjects in Research Establishing an Institutional Animal Care and Use Committee” and this SOP detail the policies and regulations governing research conducted using animals and the requirements for submitting research proposals for review by the LSCDVAMC R&D Committee and the IACUC.

These policies and procedures present the most current information for reference by investigators and their staff. This is not however, a static document. The policies and procedures are reviewed for adequacy annually by the R&D Committee. Revisions to the SOPs are made by the ACOS/R, reviewed, and approved by the IACUC, and final approval is given by the R&D Committee. The ACOS/R will keep the research community apprised of new information that may affect the ACUP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through the VA electronic mailing system. The policies and procedures are available on the LSCDVAMC Intranet website (http://vhacleweb2.v10.med.va.gov/cleveland_internet_tmp/research/research/), the LSCDVAMC Internet website (http://www.cleveland.va.gov/research/index.asp), and copies are available upon request.

1.15 ACUP Organization (Appendix 1)
The ACUP is a comprehensive system to ensure the protection of animals used in research. The ACUP is a multi-tiered program involving the following:
- Medical Center Director
- Chief of Staff (COS)
- Associate Medical Center Director
- Research Service
  o Associate Chief of Staff for Research and Development (ACOS/R)
  o Administrative Officer for Research and Development (AO/R)
  o Research and Development (R&D) Committee
    - R&D Committee Coordinator
  o Institutional Animal Care and Use Committee (IACUC)
    - IACUC Coordinator
  o Animal Research Facility (ARF)
  o ARF Supervisor
  o Animal Care Technicians
  o Attending and Consulting Veterinarian(s)
  o Subcommittee on Research Safety (SRS)
  o Research Safety Coordinator/Chemical Hygiene Officer (RSC)
  o Animal Care and Use Program Committee
Conflict of Interest (COI) Committee
Research Compliance Officer (RCO)
  - Conflict of Interest (COI) Administrator
Research Credentialing Coordinator (RCC)
Research Information Resource Manager (RIRM)
Executive Director, Staff, and Board of Directors of the Cleveland VA Medical Research and Education Foundation (Foundation)
Investigators
Study Staff
- Other Medical Center Services, Committees and/or Employees
  Medical Executive Committee (MEC)
  Pharmacy Service
  Environment of Care (EOC) Committee
  Engineering Management Service
  Radiation Safety Committee
  - Radiation Safety Officer (RSO)
  Information Security Officer (ISO)
  Regional Counsel’s Office
- Other Institutions and Committees
  Case Western Reserve University (CWRU) and the CWRU IACUC
  CWRU Conflict of Interest Committee (COIC)
  CWRU Institutional Biosafety Committee (IBC)

The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of animals used in research.

The following officials, administrative units, and individuals have primary and secondary responsibilities for implementing the ACUP:

1.16 Institutional Responsibilities
It is the responsibility of the LSCDVAMC to formally assure the VA and other Federal agencies in writing that it will comply with regulations governing the care and use of animals in research. As part of the written PHS assurance to the government, the LSCDVAMC has developed SOPs for conducting animal research in a responsible and ethical manner.

1.16.1 Medical Center Director
VA policy at VHA Handbook 1200.3 requires that the Medical Center Director serve as the IO for LSCDVAMC’s PHS assurance. Consequently, the Medical Center Director is fully responsible for overseeing the protection of animals used in research within LSCDVAMC, including:

- Establishing the institutional climate and providing institutional commitment to humane animal care and use through the IACUC. The LSCDVAMC has one IACUC.
- Overseeing the development, management, and implementation of LSCDVAMC policies governing the R&D Committee, IACUC, all LSCDVAMC animal research, and all LSCDVAMC investigators and study staff. This includes monitoring changes in regulations and policies that relate to the ethical treatment and use of animals in research and overseeing all aspects of the ACUP.
- Maintaining open channels of communication among all parties involved in the LSCDVAMC ACUP.
- Ensuring that the LSCDVAMC IACUC is provided with adequate administrative support and personnel to support the review and record-keeping functions of the IACUC (includes timely preparation of minutes and timely preparation of investigator correspondence and other documents) and has the resources and support necessary to comply with all federal regulations and guidelines that govern animal research.
- Overseeing the operation and administration of the LSCDVAMC IACUC and determining that the IACUC functions in accordance with the assurances provided in compliance with all Federal, State, and local laws and regulations that govern the use of animals in the conduct of research.
- Meeting with the IACUC Chair, the CVMO, and the ACOS/R or representative in a face-to-face meeting to review, discuss, and sign the VA IACUC Semi-Annual Program and Facility Self-Assessment Reviews.
- Assuring that IACUC members and investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.
- Developing and implementing an educational plan for IACUC members, staff, and investigators.
- Establishing and maintaining policies to ensure that the LSCDVAMC IO, ACOS/R, R&D Committee Chairperson, IACUC Chairperson, RCO, and Regional Counsel are promptly notified regarding (1) Any serious or continuing non-compliance with PHS Policy (including any serious deviation or continuing non-compliance with the provisions of the Guide, as required by the PHS Policy) or USDA AWAR; (2) Suspensions of protocols previously approved or suspensions of procedures or studies never given approval; (3) Failure to correct a significant deficiency (identified during a semi-annual IACUC program or facility self-assessment review) according to the schedule approved by the IACUC.
- Ensuring notification of ORO, AAALAC, OLAW, USDA, funding agency, and VACO of any of the above incidents in accordance with applicable Federal regulations. Such notice will be accomplished in coordination with the ACOS/R, R&D Committee Chairperson, IACUC Chairperson, and RCO.
- Overseeing the development and implementation of a program for personal hygiene, protective safety measures, safe use of hazardous materials, and preventive medicine for personnel engaged in the care and use of research animals.
- Overseeing implementation of a research compliance monitoring process (Research Quality Improvement Program (QIP) governed by the Research QIP Oversight Committee) that provides monitoring reports, as appropriate, to the IO, ACOS/R, RCO, R&D Committee Chairperson, and IACUC Chairperson.
- Submitting, implementing, and maintaining an approved assurance through the VISN Network Director, ORO, and the PHS OLAW.
- Appointing Committee members, and Chairpersons and Vice-Chairperson(s) for both the R&D Committee and IACUC upon recommendation from the R&D Committee.
- Approving requests for tours of the animal research facility by members of the media and persons claiming to represent animal rights and animal welfare organizations.
- Reviewing, approving, and signing the final R&D Committee meeting minutes.
The Medical Center Director delegates the responsibility for the LSCDVAMC R&D program to the ACOS/R, who is advised and assisted by the R&D Committee. The R&D Committee, which reports to the Medical Center Director, oversees the IACUC.

1.16.2 Chief of Staff (COS)
The Chief of Staff (COS) has overall responsibility for all clinical activities under the purview of the LSCDVAMC. The COS provides guidance and is the direct supervisor of the ACOS/R. He/she reviews problems and issues related to the animal care and use program that is brought to his/her attention by the ACOS/R and others. The COS serves as a consultant member of the R&D Committee. The COS apprises the Medical Center Director of issues of significance.

1.16.3 Associate Medical Center Director
The Associate Medical Center Director is responsible for all of the administrative services of the medical center.

1.16.4 Research Service
1.16.4.1 Associate Chief of Staff for Research and Development (ACOS/R)
The ACOS/R is delegated responsibility for the daily management of the LSCDVAMC R&D program, including the operations of the animal care and use program and the IACUC. The ACOS/R reports to the Medical Center Director through the COS and is responsible for:
- Implementing the institutional ACUP policy.
- Ensuring that the administrative structure is in place and functioning effectively to carry out the research mission of the medical center and is in compliance with the regulations.
- Acting as liaison between VHA ORD and the LSCDVAMC R&D Committee, as well as advising the Director on key matters regarding research at LSCDVAMC.
- Administering the LSCDVAMC R&D Program, including the R&D Committee and its subcommittees.
- Overseeing the financial management of the LSCDVAMC R&D Program.
- Assisting investigators in their efforts to carry out the VA research mission.
- Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.
- Developing training requirements as required and as appropriate for investigators, subcommittee members, and study staff, and ensuring that training is completed on a timely basis.
- Maintaining accurate, up-to-date records regarding mandatory training and certification of R&D members, IACUC members, Animal Research Facility employees, and Veterinarian(s), investigators, and study staff in the protection of animals involved in research.
- Providing direct supervision of the ACUP Veterinarian(s).
- Developing and implementing a written plan of providing adequate veterinary care to laboratory animals. This plan must include the frequency of visits, provisions for after hours, weekend, and holiday veterinary coverage, and the veterinarian’s role in the ARF, as well as IACUC participation. A copy of this plan must be maintained locally, and be provided to the CVMO upon request.
- Communicating, along with IACUC representatives, with the Medical Center Director in a face-to-face meeting to review and discuss the Semi-Annual Program and Facility Self-Assessment Reviews.
- Serving as executive secretary of the R&D committee.

The Office of the ACOS/R is responsible for informing and instructing all eligible VA employees of the policies and procedures for obtaining approval to conduct research.

1.16.4.2 Administrative Officer for Research and Development (AO/R)
The AO/R supervises the day-to-day operations of the Research Office and provides staff support to the R&D Committee and the IACUC. The AO/R is expected to be knowledgeable of Federal-wide requirements provided in both regulations and interpretations for conducting animal research and to use this knowledge to advise the ACOS/R, the IACUC, and investigators concerning relevant issues. The AO/R is responsible for ensuring that a) R&D Committee meetings are scheduled, b) review materials are complete and distributed prior to the meetings for review, c) minutes are recorded accurately, d) decisions are communicated to investigators in a reasonable time, e) reports are obtained and generated on time, and f) records are maintained.

1.16.4.3 Research and Development (R&D) Committee
The LSCDVAMC R&D Committee provides overall direction and oversight of the LSCDVAMC R&D Program and is responsible for maintaining high scientific standards throughout the program. These include ensuring the scientific and ethical quality of VA research projects, the welfare of laboratory animals, the safety of personnel engaged in research, the protection of human subjects in research, security of VA research data, and the security of VHA research laboratories. The R&D Committee plays a crucial role in the establishment and development of the ACUP (See medical center policy 151-001 “Research and Development Committee” for a more detailed description of the R&D Committee).

All proposed research involving animals must be reviewed and approved by the IACUC. The R&D Committee is responsible for:

- Providing oversight of the ACUP, including an annual review and evaluation of:
  o The budget allocated for the ACUP
  o The adequacy of IACUC membership, qualification and experience of the IACUC Chairperson and Vice-Chairperson(s)
  o The adequacy of IACUC policies and procedures as needed.
  o The adequacy of the number of IACUCs in relation to the amount and types of research conducted.
  o The adequacy of IACUC staffing and space considerations.
  o The frequency and times of IACUC meetings for adequacy in relation to the amount and types of research conducted.
  o The recommendations of the IACUC and the Research QIP Oversight Committee on quality assurance and quality improvement activities.
  o Investigator compliance with ACUP and IACUC requirements.
  o The annual ACUP goals and objectives.
- Reviewing and approving the IACUC minutes.
- Maintaining high standards for the quality of the research and for the review of each project prospectively and at least annually to ensure the scientific merit, the welfare of laboratory animals, and to ensure the implementation of adequate safety measures for study staff.
- Reviewing and approving all ACUP policies and standard operating procedures.
- Reviewing the Semi-Annual Program and Facility Self-Assessment Reviews.
- Reviewing and approving per diem rates for use of the animals in the research facility.
- Reviewing the actions taken by the IACUC with regard to conflicts of interest involving study staff. The R&D Committee will determine what actions, in addition to those required by the IACUC, and should be taken by the institution or the investigator to manage, reduce, or eliminate the conflict of interest.
- Evaluating potential institutional conflicts of interest and determining what actions are required to avoid, or to appropriately manage, apparent institutional conflicts of interest.

The ACOS/R provides an annual ACUP budget report to the R&D Committee for review and approval. Any issues regarding the ACUP are brought forward to the R&D Committee as a formal agenda item.

1.16.4.4 Institutional Animal Care and Use Committee (IACUC)
LSCDVAMC has one IACUC, appointed by the Medical Center Director, acting as a subcommittee of the R&D Committee. The IACUC prospectively reviews and makes decisions concerning all animal research conducted at its facilities or by its employees or agents, or under its auspices. The IACUC is charged with ensuring compliance with animal research regulations and guidelines. It discharges this duty by complying with the requirements of the Public Health Service (PHS) Policy, the Animal Welfare Act (AWA), the Guide for the Care and Use of Laboratory Animals (the Guide), the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC), and VA regulation, guidance, and documents. See Section 2 for a detailed discussion of the IACUC.

1.16.4.4.1 IACUC Coordinator
The IACUC Coordinator:
- Directs, coordinates, and oversees all IACUC functions and operations.
- Facilitates communications between investigators and the IACUC.
- Ensures that documentation of animal research education is maintained, updated, and current.
- Ensures that study staff listed on the ACORP have completed the research education requirements.
- Oversees and ensures that: a) IACUC meetings are scheduled, b) meeting agenda is prepared, c) review materials are complete and distributed for review prior to the meeting, d) decisions are communicated to investigators in a reasonable time, e) minutes are recorded accurately f) reports are obtained and generated on time, and g) records are maintained.
- Provides regulatory, ethical, and method advice to investigators, staff, and students in preparation of application for research protocols involving animal subjects.
- Advises and educates investigators and study staff regarding operational procedures for obtaining and maintaining approval to conduct research.
- Remind Investigators of deadlines for annual reviews and expiration dates of protocols and annual training, although the Investigator has responsibility for timely completion of annual reviews and renewal submissions.
- Informs the IACUC Chair, ACOS/R, and CVMO when annual reviews and training are not completed by deadline, although the IACUC and IO have responsibility for termination of a protocol or other actions.
- Assists in program development, implementation, and evaluation by the Animal Care and Use Program Committee.
- Maintains a computerized database for tracking purposes that allows for efficient document flow and maintenance of all IACUC activity.
- Maintains quality control of IACUC support functions.
- Updates manuals and SOPs.
- Ensures that documentation of IACUC activities and decisions satisfies all regulatory requirements.
- Assists in regulatory site visits.

1.17 Animal Research Facility (ARF)
1.17.1 ARF Supervisor
The Animal Research Facility Supervisor is responsible for the day-to-day management of the ARF, including supervision of the Animal Care Technicians. The duties encompass administrative functions, personnel management, animal care, ordering animals, record keeping, equipment maintenance, and supply inventory.

1.17.2 Animal Care Technicians
The Animal Care Technicians are responsible for receiving animals, the general daily handling, feeding and housing of various species of laboratory (research) animals housed in the ARF. The duties encompass physical care of the animals, cleaning and sanitation of cages and facilities, direct handling of the animals, and equipment and physical plant maintenance.

1.17.3 Veterinarian(s)
The Veterinarian(s) are members of the Research Service under the oversight of the ACOS/R, and are responsible for implementation and oversight of the ACUP at the LSCDVAMC, and have the authority to assess the adequacy of animal care and use at the LSCDVAMC. This includes animal husbandry and nutrition, sanitation practices, zoonoses control, and hazard containment. Functions as a voting member of the IACUC. Provides a veterinary consult prior to the submission of all ACORPs. Serve as a resource for information on comparative medicine and humane methods of experimentation. Has access to all animal housing and use areas. Provide emergency veterinary care outside of normal working hours. Oversees the daily care of all research animals. Provides oversight and guidance in diagnosis and treatment of animal disease. Provides oversight/guidance for surgery programs and pre/post-surgical care. Provides oversight/guidance for anesthesia, analgesia. Provides oversight/guidance for euthanasia procedures. Provides orientation and hands on training to new investigative staff. Provides educational training to all investigative staff by giving seminars on topics in the area of laboratory animal care and use. Conducts compliance surveillance and oversight of experimentation in progress.

1.18 Subcommittee on Research Safety (SRS)
The SRS is a subcommittee of the R&D Committee. It is the research organizational unit charged with reviewing all research activities which involve biological, chemical, physical,
and radiation hazards. It reviews and acts upon all active research protocols annually, and provides written notification to the R&D Committee.

1.18.1 Research Safety Coordinator/Chemical Hygiene Officer (RSC)
The RSC coordinates all safety activities in the research laboratories by ensuring coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety Officer and/or Radiation Safety Committee and the Environment of Care (EOC) Committee. The RSC reviews, prepares, and records information for the SRS. The RSC ensures that a complete list of all products that contain chemical designation or identified by Occupational Safety and Health Administration and/or the Environmental Protection Agency as hazardous have been submitted to him/her for review and approval. The RSC also coordinates all safety-related activities in research laboratories including: mandatory safety training, safety inspections, reporting accidents, and acting as a liaison for activities with all facility security and safety committees and officials. Additionally, the RSC assures that all laboratory personnel receive annual training specific to research activities, and evaluates, on an annual basis, the effectiveness of the laboratory’s Chemical Hygiene Plan.

1.19 Animal Care and Use Program (ACUP) Committee
The Animal Care and Use Program (ACUP) Committee acts as an advisory committee to the Research & Development Committee (R&DC) and the IACUC. The committee meets at least quarterly to review initiatives and activities involving the ACUP. Topics for review and discussion may include, but are not limited to, program accreditation, review of existing policies, development of new policies, quality improvement activities, educational initiatives, committee membership, resources, and compliance.

1.20 Conflict of Interest (COI) Committee
The COI Committee is responsible for assisting the COI Administrator in working with investigators, study staff, and committee members of the R&D and IACUC to manage any potential conflict of interest risks in animal research.

1.20.1 Conflict of Interest (COI) Administrator
The COI Administrator is responsible for conducting the review process for conflicts of interest, including initial review of the disclosure forms prior to R&D Committee review, and determines whether a referral to the COI Committee is deemed necessary. He/she serves as staff for the review process; maintains records and official files for the conflict of interest process.

1.21 Research Compliance Officer (RCO) / Research Compliance Auditor (RCA)
The RCO is responsible for ensuring compliance with federal regulations, state law, VA policy and guidelines, and LSVDVAMC policies and procedures for all research conducted at the LSVDVAMC.

The RCO is expected to keep abreast of changes to laws and regulations, and interpretations of same, and to revise local policies and procedures accordingly. The RCO monitors compliance with policies by the IACUC, Administrative staff, and Investigators, and takes immediate and appropriate actions where needed to avert noncompliance. This is accomplished in multiple ways, including regulatory audits conducted by the RCA for all research projects. The RCO develops and implements a monthly Research Forum, which
includes topics of relevance for IACUC members, administrative staff, as well as investigators and staff involved in animal research.

1.22 Research Credentialing Coordinator (RCC)
The RCC manages and coordinates a system of research credentialing that involves verifying education, certifications, and licenses for those that will work with laboratory animals. The RCC also ensures the maintenance of hard copy folders with employee information for all investigators and staff that work with laboratory animals.

1.23 Research Information Resource Manager (RIRM)
The RIRM ensures that the shared database that records the credentialing and education status of every VA employee (full-time, part-time or WOC) working with laboratory animals is maintained and updated.

1.24 The Executive Director, Staff and Board of Directors of the Cleveland VA Medical Research and Education Foundation (Foundation)
The Foundation is a VA non-profit foundation established pursuant to PL 100-322 and 38 USC 7361-7368, et seq. It provides a flexible funding mechanism and, as such, facilitates approved LSCDVAMC sponsored research. The Foundation facilitates the conduct of the studies which have been approved by the LSCDVAMC R&D Committee and uses Cooperative Research and Development Agreements (CRADA).

The Foundation Executive Director works in concert with all of the components of the ACUP to ensure that research supported by this organization is carried out with the utmost protections in place for the welfare of animals. The Foundation also facilitates the distribution of research awards from itself.

1.25 The Investigator
As the individual responsible for the implementation of research, the investigator bears direct responsibility for ensuring the care of animals involved in research. This responsibility encompasses animal use protocol design, ongoing care of animals, documentation of staff training and using animals in compliance with all applicable regulations. He/she is expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing supervision of support staff. In addition to complying with all the policies and standards of the governing regulatory bodies, the investigator must comply with institutional and administrative requirements for conducting research. The investigator is responsible for ensuring that all study staff complete appropriate training and must obtain all required approvals prior to initiating research. The Investigator is responsible for timely completion of annual reviews, completion of annual training requirements for him/herself as well as his/her study staff, and submission of renewal protocols. In addition, the investigator must ensure that all members of the animal use team always comply with the requirements, policies, as well as noncompliance findings and determinations of the IACUC.

1.26 Study Staff
Every member of the study staff is responsible for the safe care of the research animals. Co-investigators, research assistants, and all other study staff have a strict obligation to comply with all IACUC determinations and procedures, adhere rigorously to all protocol
requirements, inform investigators of any unanticipated problems, and take necessary measures to ensure proper handling of research animals.

Researchers/staff at every level are responsible to promptly notify the IACUC when they become aware of any serious or continuing non-compliance with applicable regulatory requirements, and/or determinations of the IACUC, and/or failure to follow VA requirements of which they become aware, whether or not they themselves are involved in the research. Researchers/staff may also notify the RCO directly of any compliance concerns they may have. Notification may be made anonymously following the established system for anonymous notification of deviations from protocols or regulations. See section 2.5 also.

1.27 Other Medical Center Services, Committees, and/or Employees

1.27.1 Medical Executive Committee (MEC)
The MEC meets monthly and serves as the executive committee of the medical staff of the LSCDVAMC. The MEC receives, acts on, and approves criteria for granting clinical privileges for each clinical service and makes recommendations directly to the Medical Center Director regarding the structure, operations, personnel management, ethics, and self governance of the medical staff.

The MEC reviews and evaluates: a) the quality of clinical programs and the clinical performance of Medical Staff members; b) risk management activities, c) the scope, quality, and effectiveness of medical educational programs at the LSCDVAMC, d) the professional development of the Medical Staff members, and e) the scope, quality, and productivity of research programs at the LSCDVAMC.

The MEC reviews the final R&D Minutes. The ACOS/R also reports regularly to the MEC and keeps the MEC informed on research related activities and the ACUP.

1.27.2 Pharmacy Service
The LSCDVAMC Pharmacy Service supplies all drugs used in the ARF, including controlled substances. The Pharmacy Service dispenses controlled substances with VA Form 10-2638, Controlled Substance Administration Record. A representative of the Director’s Office conducts unannounced audits of narcotic usage each month. See Medical Research Service SOP SRS-16, “Controlled Substance Program: Medical Research” for more information.

1.27.3 Environment of Care (EOC) Committee
The EOC Committee analyzes information on the effectiveness of the safety, fire prevention safety, medical equipment, utilities management, security management, hazardous materials and waste management, and emergency preparedness programs of the LSCDVAMC, and makes committee recommendations for improvement in the processes of systems. The EOC conducts periodic inspections of all sites of care under the jurisdiction of the LSCDVAMC including the Research Service and the ARF.
1.27.4 Engineering Management Service (EMS)
EMS is responsible for providing inspection, installation, alteration, maintenance, and repair of the station facilities. EMS oversees the physical plant of the ARF to assure that everything is operating satisfactorily. During off days/times the EMS monitors the ARF. If problems occur, e.g., an air conditioning compressor fails, EMS personnel will advise the AO/Research who will work with the supervisor to provide an adequate environment until the repair is made. During emergency situations, Police Services will make frequent tours through the ARF to assure that essential services are being provided for the animals. If emergencies occur outside of working hours, Boiler Plant personnel will be contacted; they will call EMS personnel to resolve the problem. Medical Center Police may notify the AO/Research or the ACOS/Research.

1.27.5 Radiation Safety Committee (RSC)
The RSC oversees the use of all medical center ionizing radiations sources to ensure safe, responsible practices and full compliance with Radiation Safety Program requirements. The RSC reviews and approves or disapproves as appropriate all research protocols that involve the use of ionizing radiation. It is responsible for ensuring the safe use of all forms of ionizing radiation per applicable regulations from the Nuclear Regulatory Commission, the State of Ohio, the Department of Transportation, the FDA, Environmental Protection Agency, the Joint Commission, and the Department of Veterans Affairs.

1.27.5.1 Radiation Safety Officer (RSO)
The RSO administers, coordinates, and manages the Radiation Safety Management Program and Radiation Safety Program activities. The RSO serves as the liaison between the RSC, the IACUC, the SRS, and the EOC. The RSO keeps the RSC informed of any ionizing radiation safety issues.

1.27.6 Information Security Officer (ISO)
The ISO’s responsibilities related to the ACUP are:
- Providing guidance and assistance to the Research Office, investigators, and study staff related to research data information security.
- Providing guidance and assistance to the Research Office, investigators, and study staff in completing research data security certification checklists.
- Reviewing and, when appropriate, approving PIs’ requests for storing sensitive VA research data outside the VA.
The ISO is a consultant member of the R&D Committee.

1.27.7 Regional Counsel’s Office
The LSCDVAMC ACUP, the R&D Committee, and the IACUC rely on the VA Regional Counsel’s Office for the interpretations and applications of VA regulations, Ohio law, and the laws of any other jurisdiction where research is conducted as they apply to animals used in research.

1.28 Other Institutions and Committees
1.28.1 Case Western Reserve University (CWRU) and the CWRU IACUC
CWRU is the primary academic affiliate of the LSCDVAMC and administers research funding for non-VA federal sources. As stipulated by federal regulations, it is the responsibility of CWRU, the grantee, to oversee all of its ongoing research. In light of this
responsibility, a representative from the CWRU IACUC is a non-voting member of the LSCDVAMC IACUC.

Animals belonging to CWRU may be housed at the LSCDVAMC and animals belonging to the LSCDVAMC may be housed at CWRU. The LSCDVAMC has an MOU with the CWRU that outlines the responsibilities of each party. Since 1978, the LSCDVAMC has had arrangements with CWRU Animal Resource Center (ARC) to allow CWRU to purchase and house animals to be used by LSCDVAMC investigators on VACO-approved Merit Review Programs. It has been CWRU’s policy that, since the day-to-day responsibility for the welfare of these animals devolves to CWRU ARC, and their IACUC, CWRU also assumes ownership.

The LSCDVAMC maintains a strong association with the CWRU ARC and strives to standardize, as much as possible, the animal care and use practices for the CWRU owned animals housed at the VA. As such, a representative from the CWRU IACUC is a non-voting member of the LSCDVAMC IACUC, and a representative from the LSCDVAMC IACUC is a non-voting member of the CWRU IACUC. Each IACUC shares with the other IACUC meeting minutes, semiannual inspection reports, and reports of any noncompliance investigations at the LSCDVAMC involving CWRU administered studies or at CWRU involving VA funded studies.

In addition, the LSCDVAMC works very closely with CWRU’s Research Compliance Office to ensure conflict of interests are disclosed properly and adequately, and that other preventative steps are taken to ensure the integrity and quality of research.

1.28.2 CWRU Outside Interests Committee (COIC)
The COIC is composed of CWRU faculty, CWRU representatives from Research Administration, Technology Transfer, and Finance and Administration, and compliance representatives from CWRU’s affiliated hospitals. The CWRU Offices of General Counsel and Internal Audit participate in an advisory, non-voting capacity, as well.

The primary duties of the COIC include the ongoing development of conflict of interest policy and procedures for CWRU, coordination of these policies and procedures with the affiliate/partner hospitals, review of conflict of interest disclosures submitted by CWRU Faculty and investigators on sponsored research, and the development of conflict of interest management plans, in consultation with CWRU Deans and Department chairs, as necessary.

1.28.3 CWRU Institutional Biosafety Committee (IBC)
The CWRU Institutional Biosafety Committee (IBC) reviews, approves, and oversees projects involving recombinant DNA in accordance with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA. The LSCDVAMC has an MOU with CWRU to utilize their IBC in the event that recombinant DNA research is conducted under the auspices of LSCDVAMC.
1.29 Relationship among Components
The interaction and relationships among the ACUP components is a continuous and evolving process, occurs routinely and on multiple levels, and is managed through a number of mechanisms, including convened standing committee meetings, overlapping membership on local committees, regular correspondence usually via email, and informal associations among individuals that are part of the ACUP.

1.29.1 Interaction within the Research Service
A biweekly “Research Service Staff Meeting” is held to discuss the ongoing initiatives of the R&D program. This forum allows for an exchange of information from the various individuals and committee representatives involved in the ACUP (ACOS/R, AO/R, Research Administrative Staff, IACUC Coordinator, RCO, RSC, RIRM, RCC, R&D Committee Coordinator, and the Foundation Executive Director).

The ACUP Committee meets at least quarterly to exchange information and formulate corrective action plans for recommendation to the IACUC and other committees.

The Research QIP Oversight Committee meets at least quarterly to discuss the details of the Research QIP, with the ACUP being one component of the program. This committee provides for evaluation and improvement activities concerning all research activities, including the ACUP. Members of this committee include, ACOS/R, AO/R, RCC, R&D Committee Coordinator, RCO, RSC, IACUC Coordinator, IRB Administrator, and IRB Coordinator.

1.29.2 Interaction between the Research Service and the rest of the ACUP
The R&D Committee Coordinator and the IACUC Coordinator interact routinely and regularly with the IACUC/R&D Committee Chairpersons/Vice-Chairperson(s) and Chairperson of the SRS as needed: a) prior to the respective committee meetings to prepare and review the agenda, b) during the meeting while the review process is ongoing, and c) after the meeting for the generation of decision letters.

The RCO, the R&D Committee Coordinator, and IACUC Coordinator belong to the preliminary administrative review team (PART). This informal team provides a preliminary review of new research protocols to determine if all necessary requirements for submission have been fulfilled. The PART may consult other members of the administrative research team (IACUC Chairperson, R&D Chairperson, RSC, Executive Director of the Foundation, etc.) as deemed necessary.

Communication and interaction with the Pharmacy Service is provided by the IACUC Coordinator and the Pharmacy.

Communication and interaction with the Engineering Management Service is provided by the IACUC Coordinator and the Pharmacy.

Research information security review, information, and concerns are addressed by the medical center ISO. The ISO is a consultant member of the R&D Committee.
The Radiation Safety Officer (RSO) is the representative for communications with the RSC. The RSO is a member of the Radiation Safety Committee, a voting member of the SRS and the EOC Committee.

The ACOS/R is a member of the MEC, which includes the Medical Center Director and the COS. During this meeting, the ACOS/R provides updates on the overall research activities including the ACUP.

The IACUC/R&D Committee Chairpersons and Vice-Chairperson(s) have direct access to the COS and Medical Center Director. PIs have direct access to the COS. Meetings related to the ACUP occur as needed on the request of the COS, the PI, or IACUC/R&D Committee Chairpersons, and Vice-Chairperson(s).

EOC Committee communication and information exchange is provided by the RSC and the Radiation Safety Officer who serve as members of the EOC.

The Research Service provides Research Forums that allow for an exchange of information among Research Service Leadership, investigators, and study staff.

1.29.3 Interaction among committees:
The R&D Committee meeting provides a venue for interaction and communication with other components of the ACUP. Members involved are: ACOS/R, AO/R, RCO, IACUC Vice-Chairperson, R&D Chairperson, Foundation Executive Director, a Pharmacy Service Representative, SRS Chairperson, RSC, R&D Committee Coordinator, COS, Medical Center Director, and the Information Security Officer.

1.29.4 Protocol-specific coordination
The “Request to Review Research Proposal (RRRP)” form, which must be submitted with every protocol, requires PIs to indicate institutional support required for the research from the following services:
  - Laboratory
  - Medicine
  - Pharmacy
  - Radiology
  - Nuclear Medicine
  - Nursing
  - Psychiatry
  - Outpatient
  - Surgery
  - Other

For each service indicated, a letter of support or collaboration from the respective Service Chief must be included with the RRRP. The protocol will be reviewed in the R&D and IACUC Offices to ensure that all correspondence is included.
1.29.5 Interactions with CWRU
As noted above, a representative from the LSCDVAMC IACUC is a non-voting member of the CWRU IACUC and a representative from the CWRU IACUC is a non-voting member of the LSCDVAMC IACUC. These interactions provide a means for information sharing and discussion related to animal care and use programs.

The LSCDVAMC RCO is a voting member of the COIC. This forum allows for a coordinated review of potential investigator conflicts among the CWRU affiliated institutions and provides a means of sharing investigator management plans with the affected affiliate.

In the event that recombinant DNA research is conducted under the auspices of the LSCDVAMC, the LSCDVAMC will rely on the review of the CWRU IBC. As per the Memorandum of Understanding (MOU) with CWRU, the LSCDVAMC SRS Chairperson will be present at the CWRU IBC meeting when a LSCDVAMC study is reviewed. This mechanism allows the LSCDVAMC to be in compliance with NIH and VHA Handbook 1200.8 “Safety of Personnel Engaged in Research” Appendix C (4). In addition, this process provides coordinated review and communications between the CWRU IBC, the SRS, the IACUC, the PI, and the R&D Committee.

1.30 Operations
In addition to the leadership structure described above, other support staff members for the ACUP, a full-time R&D Committee Coordinator, and a full-time Research Service Program Assistant.

1.30.1 R&D Committee Coordinator
The R&D Committee Coordinator is responsible for providing administrative and clerical support to the R&D Committee, as well as the scheduling and coordination of the activities of the R&D Committee. He/she ensures that each study receives all appropriate reviews and approvals prior to providing final R&D Committee approval to the investigator.

1.30.2 Research Service Program Assistant
The Research Service Program Assistant provides administrative and clerical support to the ACOS/R, AO/R, R&D Committee Coordinator, RCO, and R&D Committee.

1.31 Selection, Supervision and Evaluation of Supporting Staff
1.31.1 Selection Process:
LSCDVAMC follows Human Resources Management Services (HRMS) rules and regulations concerning selection, supervision, and evaluation of R&D staff in general and the ACUP support staff. Vacant positions are announced locally and nationally. Initial selection of candidates is done by HRMS to conform to the position description. These candidates are then interviewed by the ACOS/R, the AO/R, and the other ACUP staff, as appropriate. A qualified candidate is then selected and is notified by HRMS.
1.31.2 Supervision:
The LSCDVAMC provides a new employee orientation program for the selected candidate. In addition, the selected candidate attends the New Employee Research Safety Orientation presented by the RSC. Continuous mentoring and supervision is done on a daily basis until the candidate is deemed capable of handling the assigned tasks. In general, the AO/R directly supervises all the R&D office staff and the IACUC Coordinator. The ARF Supervisor supervises the Animal Care Technicians. The ACOS/R supervises the AO/R, the RCO, and the Veterinarian(s). The ACOS/R reports directly to the Medical Center Director through the COS.

1.31.3 Evaluation:
Overall, employee evaluation is an ongoing process as areas of improvements are identified and corrective actions are put in place. Formally, for new staff, there is a 90-day evaluation requested by HRMS. All staff receives a mid-year performance appraisal, during which the supervisor discuss positive achievements and areas of improvements. An annual performance appraisal is also conducted and final ratings are completed.

1.32 ACUP Financial Support
Funding from VA Central Office provides the majority of financial support for the ACUP. Additional monies come from animal per diems. Funds from VACO provide the revenue required to support the Research Administrative Office, which includes the IACUC component. The Medical Center Director supports the salary of the RCO.

VACO-allocated funds also support the non-personnel and infrastructural needs of the ACUP program which include: office space and IT equipment, Xerox maintenance, paper, postal and shipping expenses, education and training, and reimbursement for non-VA IACUC members to defray travel costs. The medical center provides space for conferences and meetings and audio-visual equipment.

The AO/R ensures that the ACUP funding allocation is conducted on a timely and appropriate basis.

1.33 ACUP Facilities
The R&D Service, including the ACUP, is located at the LSCDVAMC Wade Park Facility and the Brecksville Facility.

The adequacy of personnel and non-personnel resources of the ACUP program is assessed on an annual basis by the ACOS/R with the ACUP staff and are reviewed and approved by the R&D Committee.

1.34 Institutional Animal Care and Use Committee (IACUC)
1.34.1 Purpose
The following describes the authority, role, and procedures of the LSCDVAMC IACUC. The IACUC is established to oversee the LSCDVAMC’s animal research program, facilities, and procedures.

1.34.2 Number of IACUCs and Meeting Schedule
There is currently one medical center-wide IACUC serving the LSCDVAMC. The VA does not serve as the IACUC of record for any other VA or non-VA facility and/or institution.
The IACUC holds a convened meeting monthly.

1.34.3 Responsibilities of IACUC
The LSCDVAMC IACUC must perform the review and oversight functions required by PHS Policy, the Guide, the Animal Welfare Act, the USDA AWAR, VA policy, and any other Federal regulations that impact IACUC function. The IACUC reports to the R&D Committee and the IO.

Responsibilities of the IACUC are as follows:

- Oversee and evaluate the institution’s Animal Care & Use Program.
- Assure that all activities involving animals meet the ethical and legal requirements for the humane care and use of animals.
- Conduct semi-annual evaluations of the ACUP as well as the ARF, associated animal use labs where animals are housed more than 12 hours, and other procedure areas at the LSCDVAMC, using the Guide as a basis for evaluation,
- Inspect at least once every six months all of the institution’s animal facilities (including satellite facilities) using the Guide as a basis for evaluation.
- Conduct oversight and evaluation of the ACUPs and facilities at other institutions that house VA animals or, alternatively, reviews and evaluates the semi-annual reviews of another IACUC in lieu of its own review of those programs.
- Approve reports of the IACUC semi-annual evaluations conducted and submit the reports to the Institutional Official.
- Review and approve, require modifications, or withhold approval of all protocols involving the use of animals in research, teaching, or training.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
- Review and approve or withhold approval for all previously approved animal protocols on an annual basis.
- Review and investigate legitimate concerns involving the care and use of animals under the auspices of the LSCDVAMC.
- Make recommendations to the Institutional Official regarding any aspect of the institution’s animal program, facilities, or personnel training.
- Suspend an activity involving animals when necessary and take corrective action and report findings and actions through the IO to all appropriate regulatory, funding, and accrediting agencies.

1.34.4 IACUC Member Roles and Responsibilities/ Composition of the IACUC
The composition of the IACUC must meet existing requirements set forth in the Animal Welfare Act and PHS Policy.

Only a properly constituted IACUC may conduct official business. A minimum of five members are required to serve as voting members to constitute an IACUC. The required voting members include:

- Chairperson
- Attending Veterinarian
- One scientist with animal research experience
- A non-affiliated community member
- A lay member (who must not be involved in animal research).
At least one member of the IACUC must be a voting member of the R&D Committee. At least one member of the IACUC must be a voting member of the Subcommittee on Research Safety.

The designation of lay members as both the lay member and the non-affiliated member is discouraged. Recruitment of separate individuals to fulfill these roles is a best practice.

1.34.4.1 IACUC Chairperson
The IACUC Chairperson needs to be a more senior scientist with animal research experience and good committee management skills. The IACUC Chairperson:

- Plays a leadership role in establishing and implementing IACUC policy in conjunction with the IACUC Members, IACUC Coordinator, R&D Committee, ACOS/R, COS, and Medical Center Director.
- Evaluates and champions policy and practice initiatives to improve the animal care and use program
- Represents the IACUC in discussing IACUC decisions with researchers.
- Represents the IACUC in discussions with other segments of the organization.
- Represents the LSCDVAMC in discussions with federal and regulatory authorities.
- Directs the proceedings and discussions of the convened IACUC meeting. This includes keeping the discussion focused on important IACUC issues and ensuring that the convened committee meeting process is both efficient and effective.
- Serves as an IACUC voting member and assumes all the responsibilities as such.
- Assisted by the IACUC Coordinator, assigns reviewers of protocols whether for designated review or full committee review.
- Demonstrates an in-depth understanding of ethical issues, federal, state, and VA regulations, medical center policies, animal welfare policies, procedures, and guidelines to protect animal subjects and to ensure institutional compliance.
- Calls for special meetings when appropriate and necessary.
- Appoints IACUC members and nonmembers as needed to serve on subcommittee(s) of the IACUC for specific purposes such as investigation of alleged noncompliance or significant deficiencies and development of IACUC review guidelines for specific types of protocols such as those involving type E procedures. The IACUC, lead by the chair, drafts the specific mission and/or goals for each subcommittee.
- Consults the IACUC Coordinator to ensure that the operation of the IACUC is within all applicable regulatory requirements.
- Ensures the establishment of a written system of communication for the IACUC with the investigators concerning the approval status of protocols and the steps necessary to secure approval.
- Reviews and signs the IACUC minutes that document a summary of the protocol, pertinent IACUC discussions, issues, and concerns raised by the IACUC, and actions and reasons for the actions taken by the IACUC.
- Recommends the appointment of a Vice-Chairperson(s) to the R&D Committee following consultation with and in agreement with the other members of the IACUC. The Vice-Chairperson(s) will be a senior member of the IACUC who will assume the responsibilities of the Chairperson during any period of the Chairperson’s absence.
- Educates and supports IACUC members, PIs and others regarding the IACUC process.
- Signs correspondence on behalf of the IACUC.
- Notifies the RCO of any research-related complaints and allegations of noncompliance with ACUP institutional policies that have been raised by any individual. The IACUC Chairperson will review any inquiries and reports brought forth to him/her by the RCO following investigations of incidents of noncompliance. The IACUC Chairperson will determine if it is necessary to convene a special session of the IACUC or to wait until the next convened meeting.
- Reports to appropriate regulatory agencies and organizations, when necessary, consistent with VA policy and federal regulations.
- Participates in semi-annual and animal facility inspections.
- Along with the CVMO and the ACOS/R or representative, presents the semi-annual review report in a face-to-face meeting with the IO.
- Communicates regularly with the IO, Veterinarians, IACUC Coordinator, and the Animal Care Technicians.
- Adheres to all policies and procedures as detailed in this document.
- Makes suggestions for amending/improving committee agendas, times and days of meetings, and other items/issues that may affect the efficient operation of the IACUC.

The IACUC Chairperson cannot simultaneously chair another research subcommittee.

The Medical Center Director may relieve an individual as IACUC Chairperson for failure to fulfill the duties listed above. The Medical Center Director may remove the Chairperson from the IACUC for a) failure to perform the duties of an IACUC member, including failure to attend at least 2/3 of the IACUC meetings held within any 12-month period; or b) for scientific misconduct; c) conflict of interest; or d) argumentative behavior such that review of research by the IACUC is made difficult or impossible.

1.34.4.2 IACUC Vice-Chairperson
The Vice-Chairperson(s) responsibilities are as follows:
- Serves as an IACUC voting member and assumes all the responsibilities as such.
- Perform the responsibilities of the Chairperson in his/her absence.
- Sign correspondence on behalf of the IACUC.
- Assist the Chairperson as needed.
- Serve as a voting member of the R&D Committee.

1.34.4.3 IACUC Members
IACUC Member responsibilities are as follow:
- Assure that the rights and welfare of animal subjects are protected.
- Participate in training and continuing education on ethical, legal, and regulatory issues related to the IACUC.
- Complete the annual animal education requirements “Essentials of the VA IACUC” on an annual basis.
- Review assigned protocols and serve as a designated reviewer when appropriate.
- Maintain appropriate confidentiality of the information contained in any and all reviews.
- Listen and take part in active IACUC discussions and contribute in his/her area of expertise as appropriate. When appropriate, asking questions for clarification to aid in the decision-making process.
- Make an informed vote to approve, require modifications, defer for major modifications, or withhold approval of the research protocol as presented to the convened meeting of the IACUC.
- Complete the appropriate reviewer forms in a timely manner for submission to the IACUC Coordinator.
- Avoid conflicts of interest or the appearance of conflicts of interest.
- Participate in the semi-annual facility inspection and program reviews.
- Forward any requests for consultation from investigators, study staff, and clinicians, etc. to the IACUC Coordinator for dissemination to appropriate individuals and for documented response to the individual’s questions/concerns.
- Become familiar and knowledgeable of all animal welfare research policies and procedures, and the ACUP SOPs.

1.34.4.4 Alternate IACUC Members
Nominations for alternate members are submitted by the IACUC and R&D Committee through the ACOS/R and COS to the Medical Center Director who formally appoints them in writing. Alternate members serve three-year terms and may be reappointed indefinitely. Alternate members serve in the absence of the primary IACUC member for whom they have been designated as an alternate. Typically, the alternate member serves the same term length as the primary member, usually three years. The alternate member has a similar level of expertise as the primary member for whom he/she serves as an alternate. The IACUC roster identifies the primary member for whom each alternate member may substitute.

Alternates may attend any IACUC meeting and are encouraged to attend as many meetings as possible. The alternate member will not be counted as a voting member unless the primary member is absent. However, the alternate member may freely participate in the discussion. IACUC minutes will record when alternate members act in the absence of the primary members.

1.34.4.5 Non-Affiliated Community Member
The IACUC must include at least one member who is not otherwise affiliated with the LSCDVAMC and who is not part of the immediate family of a person who is affiliated with the LSCDVAMC. The person chosen should provide representation for general community interests in the proper care and treatment of animals and therefore must not work with or have experience working with laboratory animals. For example:
- A veteran who volunteers at the LSCDVAMC is considered to have an affiliation with the institution and is disqualified from serving as the non-affiliated IACUC member. Appointment of such veterans to the IACUC in another capacity, such as lay member, is strongly encouraged.
- Veterans who do not use a VA medical center for medical care may serve as the non-affiliated member on that medical center’s IACUC, as long as they have no other affiliation with the medical center and are not immediately related to a medical center employee.
- A retired teacher or librarian with no laboratory animal experience and no personal or family affiliation with the VA medical center would qualify as a non-affiliated community member.
The designation of lay members as both the lay member and the non-affiliated member is discouraged. Recruitment of separate individuals to fulfill these roles is a best practice.

1.34.4.6 Lay Member/Non-Scientific Member
The lay member or non-scientific member is person whose primary concern is in a non-scientific area (for example, an ethicist, lawyer, or member of the clergy). Individuals may have some scientific training, but clearly do not qualify as a practicing scientist with experience in research involving animals.

1.34.4.7 Non Voting Consultant Members
Non Voting Consultant members are “non-voting” members of the IACUC and are appointed due to their position at the LSCDVAMC. These members must adhere to the same institutional, regulatory, and federal, and COI policies and procedures and are required to take the same training as voting IACUC members. These members are not nominated by the Medical Center Director. The ACOS/R, AO/R, RCO, R&D Committee Coordinator, the Research Safety Coordinator, representative of the CWRU IACUC, and a representative of the animal care technicians serve as non-voting consultant members of the IACUC.

The ACOS/R and AO/R may not serve as voting members on the IACUC.

1.34.5 IACUC Membership Procedures
IACUC members are selected based on their experience and expertise to oversee the institution's animal program, facilities, and procedures. The structure and composition of the IACUC must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at the LSCDVAMC.

The R&D Committee conducts an annual review and oversight of adequacy of IACUC membership. The IACUC members must be sufficiently qualified to review research through their experience, expertise, diversity, and professional competence.

1.34.5.1 Appointment of Members to the IACUC
The nomination for IACUC Chairperson is submitted by the IACUC and R&D Committee through the ACOS/R and COS to the Medical Center Director who formally appoints him/her in writing. The IACUC Chairperson should be a highly respected individual fully capable of managing the IACUC, and the matters brought before it with fairness and impartiality.

The IACUC Chairperson serves a one-year term and may be re-appointed indefinitely without lapses in service. There is no limit to how many times a chairperson may be reappointed, but it is best practice to rotate the Chairperson position to develop a cadre of research staff with experience filling that role.

The nomination for Vice-Chairperson(s) is submitted by the IACUC and R&D Committee through the ACOS/R and COS to the Medical Center Director who formally appoints her/her in writing. Their term is one year and they may be re-appointed indefinitely without lapses in service.
Nominations for IACUC Members are submitted by the IACUC and R&D Committee through the ACOS/R and COS to the Medical Center Director who formally appoints them in writing. Members serve three year terms and may be reappointed without lapses in service.

1.34.6 IACUC Member Conflict of Interest
No regular, alternate, or consultant member may participate in the initial or continuing review of any research project in which the member has a COI, except to provide information as requested. It is the responsibility of each IACUC voting and non-voting member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and vote by leaving the room. The Conflict of Interest form is located in Appendix 2.

In addition, the IACUC Chairperson will poll IACUC members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds them that they should recuse themselves by leaving the room during the discussion and vote of the specific protocol. IACUC members with a conflicting interest are excluded from being counted towards quorum. All recusals by members with COI are recorded in the minutes.

Committee members may find themselves in any of the following conflicts of interest when reviewing research:
- Where the member or consultant is involved in the design, conduct, and reporting of the research.
- Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research.
- Where the member holds significant financial interests in the research being reviewed.

The IACUC Chairperson or Vice-Chairperson, at the beginning of each meeting, will record in the minutes verification for each protocol that any conflicted members did not participate in discussion or vote on protocols involving their COI, except to provide information as requested.

The ACOS/R and AOR should not serve as voting members on the IACUC, and when in attendance, need to be very sensitive to the occurrence or appearance of conflict of interest relative to their supervisory, managerial, or fiscal authority. They should avoid intervention or participation in deliberations involving entities in which they have financial or economic interests, except to provide information as requested by the IACUC.

1.34.7 Use of Consultants
On an as-needed basis, the IACUC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IACUC. Consultants may provide guidance and expertise either in person or through written comment, but may not vote.

1.34.8 Compensation for IACUC Service
Non-affiliated and lay members of the IACUC may be compensated for travel expenses and time, as long as such reimbursement cannot be construed as compromising their
ability to fulfill their independent respective roles on the IACUC. Full or part-time employees of the VA and Investigators appointed without compensation (WOC) to the VA medical center are not compensated for IACUC service.

1.34.9 Continuing Education for all Animal Users
Federal law requires that the IACUC make recommendations to the IO for development and administration of animal care and use training programs for all personnel involved in the use of animals in teaching or research. Animal users require training in order to ensure that all persons involved in animal care and use are:

- Informed of IACUC and Laboratory Animal Resources (LAR) policies and procedures regarding animal care and use at LSCDVAMC
- Informed of available resources regarding animal care and use certified by accrediting and oversight agencies including AAALAC, OLAW, and the USDA
- Verified to be technically proficient and fully capable of their responsibilities for animal care and use covered under their ACORP; and
- Provided training and offered participation in the risk-based Occupational Health and Safety (OH&S) program.

1.34.10 Review of IACUC Member Performance
The R&D Committee will review IACUC members’ performance on an annual basis. The R&D Committee may recommend to the Medical Center Director that that an IACUC member be relieved of his/her service for a) failure to perform the duties of an IACUC member, including failure to attend at least 2/3 of the IACUC meetings held within any 12-month period; or (b) scientific misconduct, (c) conflict of interest, or (d) argumentative behavior such that review of research by the IACUC is made difficult or impossible.

1.34.11 Liability Coverage for IACUC Members
Actions for alleged negligence or wrongful acts or omissions of Federal employees come within the provisions of the Federal Tort Claims Act. The coverage extends to federally employed IACUC members acting in performance of their duties.

To extend coverage to non-federally employed IACUC members acting in performance of their IACUC duties, the non-federally employed IACUC members (e.g., non-affiliated or community members) shall have VA WOC appointments. VACO has concluded that WOC status does not diminish their “independent/non-affiliated” capacity as required by the animal welfare regulations.

1.34.12 Reporting and Investigation of Allegations of Undue Influence
If the IACUC Chairperson, and IACUC member, or staff person considers that the IACUC has been unduly influenced by any party, he/she shall make a confidential report to the IACUC Chairperson, R&D Committee and/or ACOS/R, depending on the circumstances. The ACOS/R will conduct a thorough investigation and report his/her findings to the Medical Center Director through the COS. Final corrective action recommended by the Medical Center Director will be taken to prevent additional occurrences.
2 IACUC Review Process
2.1 Purpose
The following describe the procedures required for the review of research by the IACUC.

2.2 Animal Care and Use Protocol Review Process
2.2.1 Pre-Review Consultation
Investigators and study staff are encouraged to meet with the R&D Committee Coordinator and the IACUC Coordinator to discuss the submission of new animal protocols. This meeting allows for study-specific consultation and guidance when preparing the ACORP. Topics addressed in this meeting include but are not limited to: a) specific questions about the IACUC and ACUP policies and procedures and b) a review of the ACORP and what appendices are required for a particular study. Investigators and study staff are encouraged to contact applicable Research Office Staff for any questions, concerns, problems, or issues related to research involving animals. The VA mandates the use of a specific review form for all animal studies - the Animal Component of Research Protocol (ACORP; Appendix 2).

2.2.2 Veterinarian Consultation
After the ACORP is initially completed, the submission receives a veterinary consultation. This review can be accomplished on-line, but may entail a meeting to address specific issues raised on veterinary review. No protocol may be placed on an IACUC agenda until a veterinary consult by one of the veterinarians has been performed. Please note that the review of a protocol by one of the veterinarians during an IACUC meeting does not satisfy this requirement.

2.2.3 Protocol Review Process
IACUC review can occur in parallel with other research subcommittees (Subcommittee on Research Safety, Radiation Safety Committee). In some cases, the IACUC will seek guidance from another research subcommittee (e.g., Subcommittee on Research Safety), prior to granting final approval. After the protocol has been approved by all subcommittees, the R&D Committee Coordinator will conduct an activation review of the project and make a final determination (VHA Handbook 1200.1 Research & Development Committee). The R&D Committee Coordinator will not grant final approval until all other approvals have been obtained and/or verified. For research administered through the Foundation, the R&D Committee Coordinator verifies that a signed agreement is on file prior to sending the R&D Committee approval letter. The PI may begin the research project once he/she has received written confirmation from the ACOS/R.

Should the IACUC, or any other subcommittee, disapprove the research, this decision cannot be overruled by the R&D Committee, the IO, or any higher authority.

2.2.3.1 New Protocol Full Committee Review of New Protocols
The PI will draft the ACORP and submit it to a veterinarian for pre-review. After an attending veterinarian has conducted a veterinary review, the protocol will be returned to the PI to address any concerns brought forth by the veterinarian. Once these concerns are addressed, the PI will forward the revised ACORP to the IACUC Coordinator. The ACORP will then be released to the IACUC committee for review. The IACUC Chair, assisted by the IACUC Coordinator, will then assign 2 primary reviewers chosen from among the voting
membership of the IACUC and the IACUC Coordinator will publish submitted ACORPs in the meeting agenda.

- IACUC primary reviewers are expected to submit comments to the IACUC Coordinator within 7 days of receipt of the ACORP for review. Additional comments can be submitted from all IACUC members.
- The primary reviewer(s) and/or the IACUC chairperson will present the ACORP to the IACUC at the convened meeting.
- A quorum of voting members present at the convened meeting vote to:
  - Approve
  - Require modifications and re-review
  - Table
  - Disapprove

ACORP approvals are submitted to the R&D committee for final project approval.

ACORPS requiring modifications and re-review will appear on the IACUC agenda following submission of a revised ACORP. The committee may use Designated Member Review (DMR) subsequent to Full Committee Review (FCR) according to the following stipulations:

- All IACUC members agree in advance in writing that the quorum of members present at a future convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
- In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW. (IACUCs that newly elect to utilize a standard operating procedure for DMR subsequent to FCR should provide information about this program change to OLAW in the next Annual Report.)

Tabled ACORPs will appear on the next IACUC agenda, following submission of a revised ACORP.

Disapproved ACORPs will not be re-reviewed or appear on the next IACUC agenda unless the reason for disapproval has been addressed and the ACORP resubmitted for review.

PIs will be notified via e-mail of IACUC decisions, within 3 working days after the IACUC meeting.

2.2.4 Designated Member Review (DMR) Process
DMR is a protocol review procedure conducted by one or more reviewers, rather than by the full committee. DMR may be used when there is no call for FCR within 7 days of notification of all members of the IACUC of the receipt of a protocol item by the IACUC Coordinator. DMR may also be used to complete the approval of a protocol item discussed at FCR when a unanimous vote of the IACUC is obtained. Designated reviewers are IACUC members who are appointed by the IACUC Chairperson, as assisted by the IACUC Coordinator. The designated reviewer assumes the responsibility of the full committee in granting approval, requiring modification, or sending the protocol for full committee review.
The DMR and approval has equal validity to approval under FCR and does not require subsequent re-approval by the full IACUC.

All continuing reviews, three-year reviews, and protocols requiring modifications and re-review are eligible for DMR if there is no call by any IACUC member for FCR within 7 days after notification by the IACUC Coordinator. Full review is used for all new protocols, and for modified Tabled and Disapproved protocols.

The following procedures will be followed when a protocol is received by the IACUC Coordinator:
- The IACUC Coordinator will send an e-mail with the ACORP attached to all IACUC members notifying them of the start of the review period.
- Members will have seven (7) days to review the protocol and return comments to the IACUC Coordinator. The IACUC Coordinator will forward all comments to the investigator to be addressed and once revised. Decisions regarding new protocols are made at a convened meeting: Approve, send to DMR, or table.
- If no member objects to DMR, the protocol will be assigned to one or more designated reviewers chosen by the IACUC Chair, as assisted by the IACUC Coordinator.
- The designated reviewer(s) will have seven (7) days to review the protocol and respond to the IACUC Coordinator with a determination.
- The designated reviewer(s) can approve the protocol as written, require revisions, or bring the protocol to full review.
- DMR may not result in withholding of approval.
- The Designated Member Reviewers must be unanimous in decision and must review identical versions of the protocol. If revisions are requested by one or more of the reviewers, then the other reviewer(s) must be aware of and agree to the revisions. If reviewers do not agree, the protocol will be reviewed by FCR.

The IACUC will be informed of the outcome of all designated reviews.

2.2.4.1 Amendments
An approved amendment is required to change approved animal procedures. Amendments must receive IACUC approval before they are initiated. Amendments are considered to fall into two categories: minor and major.

2.2.4.1.1 Minor amendments (Appendix 4) involve pre-determined aspects of research that have a low probability of impacting animal welfare and may be approved administratively following review by the IACUC Chair or Vice-Chair. These include:
- Addition of animal numbers up to and including 10% or addition of a single individual animal, whichever is greater for protocols utilizing non-USDA regulated species.
- Change in animal gender.
- Change in animal strain.
- Change in source of animals.
- Addition or changes in nonsurvival intraoperative procedures to an ACORP already approved for nonsurvival surgery.
- Change or addition of a procedural area (laboratory) for noninvasive procedure when the location is to a previously approved site.
- Change in location of an invasive procedure only when location change is to a previously approved site.
- Personnel (Limited to changes for personnel already approved for equivalent procedures in another ACORP) and not including the PI.
- Personnel roles (Limited to personnel roles not involving the role of PI or addition of roles not described for this individual in another ACORP).
- Collection of tissue after euthanasia by a method approved in the ACORP.
- Substitution of sedative, anesthetic or analgesic with a comparable agent. Must notify all relevant subcommittees of change.

2.2.4.1.2 Major amendments (Appendix 5) are reviewed in the same manner as are new protocol submissions. These include:
- Addition in number of non USDA regulated animals greater than 10% of the original number.
- Addition of 1 or more USDA regulated species.
- Changes that require Bio-Safety review.
- Requests for special housing or husbandry related to the research protocol, excluding changes deemed necessary for the best interest of the animal by the attending veterinarian.
- Substitution of sedative, anesthetic or analgesic with a non-comparable agent. Must notify all relevant subcommittees of change.
- Change of Principal Investigator.
- Any amendment the chair or veterinarian may deem necessary for IACUC review.
- Addition of procedures that change the current protocol from a lesser pain/distress category to a greater pain/distress.
- Addition of invasive or major procedures.
- Addition of surgery area not previously approved.
- Changes in housing, husbandry or enrichment that do not comply with the appropriate guide (“Guide or Ag. Guide”)

Please note that the IACUC may request that an amendment be written as a new ACORP.

2.2.5 Period of IACUC Approval
The maximum period of approval is for three years. The approval period begins on the day that IACUC final approval is determined.

2.2.6 Annual Review
All approved ACORPs require annual review and approval. Compliance with the annual review process is the responsibility of the PI. Compliance is facilitated by the IACUC Coordinator, who notifies the PI that annual review materials are due prior to the first or second year anniversary of IACUC approval. All annual review materials must be submitted to the IACUC in a timely fashion, in order to allow the IACUC to conduct the annual review prior to the end of the first or second year approval period. If the annual review process is not completed by the anniversary, no animal procedures may occur until the annual review process has been finished. This form is located in appendix 6.

2.3 IACUC Record Keeping and Required Documentation
The IACUC Coordinator provides meeting materials to IACUC members electronically and in hard copy packet. This packet includes an agenda with all business items listed and
copies of all protocol forms. Initial review of new and three-year renewals of protocols are performed by the Consulting Veterinarian. Written and/or oral comments are submitted to the PI for their review and correction where appropriate. The PI is then responsible for submitting the revised ACORP to the R&D Program Specialist for IACUC review.

Minutes summarizing the committee’s actions and discussions are distributed to committee members for review, revision as needed and approval at the next scheduled committee meeting. The IACUC minutes are formatted in compliance with the VA Handbook 1200.7.

Committee deliberations on each project must be reflected in the minutes so that an outside observer can understand the issues discussed, and recognize the specific revisions and clarifications requested for each protocol under consideration. The minutes must note when members recuse themselves to prevent conflicts of interest. If they are important to understanding the conduct of business, copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes.

Once IACUC minutes are approved, the IACUC Chairperson signs and dates the final approved version. No local official may alter the IACUC minutes once signed by the IACUC Chairperson, and no local official may exert pressure on any IACUC member to change the wording in the minutes to language more favorable to the institution. If requested by the Chief Veterinary Medical Officer (CVMO) or other VA Central Office official, complete copies of the signed minutes need to be sent through the ACOS/R and the Medical Center Director. The R&D Committee needs to review a copy of the signed minutes as an item of business, but R&D Committee approval is not necessary prior to sending minutes to ORD for review, i.e., if ORD requests a copy for review.

The following reports and correspondence must be forwarded to the CVMO’s office or ORD, as indicated:

- **USDA Annual Report of Research Facility.** This report (required by the USDA Animal Welfare Act Regulations and Standards, see Sec. 2.36) must be completed and submitted to ORD as a component of Part II of the Research and Development Information System (RDIS).
- **AAALAC Reports.** Every third year a comprehensive AAALAC Program Description must be completed prior to the scheduled triennial AAALAC site visit and annually, an abbreviated report also must be submitted to AAALAC.
- **IACUC Semi-Annual Self-Assessment Reviews.** These must be prepared by the IACUC no later than 60 days after the self-assessment review date. A copy of the approved report signed by a majority of IACUC members and the Medical Center Director must be forwarded to the CVMO’s office through the ACOS/R and the Medical Center Director.
- **Annual VA Veterinary Medical Unit (VMU) Report.** An annual VA VMU Report for the previous fiscal year must be completed using the website designed for that purpose.
- **PHS Assurances and Annual Assurance Updates.** Every fourth year, a comprehensive PHS Assurance must be completed and approved. Annually, an abbreviated report must also be submitted to PHS.
- A copy of all correspondence between Office of Laboratory Animal Welfare (OLAW), USDA, AAALAC and VA facilities must be forwarded to the CVMO and ORO within 5 business days of receipt or mailing.
This institution will maintain all reports in accordance with the record retention policy.

2.4 Education and Training for Employees Involved in Animal Research
It is the policy of The Cleveland Department of Veterans Affairs IACUC to provide and document a comprehensive training program for all animal users. Animal users require training in order to ensure that all persons involved in animal care and use are:
- Informed of IACUC and Laboratory Animal Resources (LAR) policies and procedures regarding animal care and use at The Cleveland Department of Veterans Affairs Medical Center;
- Informed of available resources regarding animal care and use certified by accrediting and oversight agencies including AAALAC, OLAW, and the USDA;
- Verified to be technically proficient and fully capable of their responsibilities for animal care and use covered under their Animal Component of Research Protocol (ACORP); and
- Provided training and offered participation in the risk-based Occupational Health and Safety (OH&S) program.

2.4.1 New IACUC members receive orientation by the IACUC Chair, Coordinator and/or the Consulting Veterinarian in areas of protocol review, inspection procedures, IACUC responsibilities and reporting requirements.

2.4.2 All IACUC members must complete the VA version of the web-based training course and exam entitled, “Essentials for IACUC Members”.

All IACUC members will receive continuing education in relevant animal use/care topics at least four times per year during the IACUC meeting. The content of the education is determined by the IACUC Chair, the IACUC Coordinator and Consulting Veterinarian.

Additional training opportunities may include:
- One-on-one training with the Chair, Consulting Veterinarian, Research Compliance Officer, or other qualified IACUC member.
- Individual review of federal, state, local or institutional laws, regulations, policies or SOPs.
- Complete web-based training courses available from VA office of Research and Development, the OLAW (PHS Policy on Humane Care and Use of Laboratory Animals tutorial), the Animal Welfare Information Center Workshop and others.
- Participate in PRIMR IACUC 101 and 201 courses.
- Educational seminars provided by the Consulting Veterinarian.
- Investigator and research staff training:
  - Investigators and research staff who utilize laboratory animals must pass the exam covering the “Working with the VA IACUC” web course, plus the exam for any species-specific web course that covered the species proposed for use.
  - New PIs, or those proposing a significant change/increase in use of the ARF, should meet with the ARF supervisor and the ACOS/R, to evaluate availability of space and facility accommodation of any special needs of their projects.
2.4.3 Animal Research Facility staff training:
The staff in the ARF must pass both the exam covering the “Working with the VA IACUC”
web course as well as species-specific to those being housed and utilized at the
LSCDVAMC.

Certificates of required training are submitted to the Research Office upon completion. The
IACUC will not approve an Investigator’s protocol unless all of the staff listed has
completed the required training. The certificates must be dated within at least one year of
the submission. These certificates serve as documentation of completion of required
training and are maintained in the Research Office.

2.4.4 Animal Research Investigator and Staff Training
New animal users must complete all phases of the training requirements prior to receiving
IACUC approval to begin research on an ACORP. All IACUC training is renewed every two
years and tracked by the IACUC Coordinator. Training may include but is not limited to:
- New Employee Safety Orientation with the Safety Coordinator
- Hands on training with the veterinarian to include a brief tour of the animal research
  facilities, basic animal husbandry, handling, health, anesthesia, analgesia and
euthanasia
- Laboratory Animal Allergy Questionnaire for Personnel Health
- Online training provided through [www.CITIProgram.org](http://www.CITIProgram.org) which includes:
  - Working with the VA IACUC
  - Orientation to the ARF
  - Occupational Health
  - Biosecurity
  - Microisolator Technique (if applicable)
  - Rodent Surgery (if applicable)
  - Post Procedural Care of Rodents (if applicable)
  - Waste Anesthetic Gas (if applicable)
  - Working with Mice in Research Settings (if applicable)
  - Working with Rats in Research Settings (if applicable)
  - Working with Dogs in Research Settings (if applicable)
  - Working with Cats in Research Settings (if applicable)
  - Working with Rabbits in Research Settings (if applicable)
  - Animal Biosafety Level 2 Policies and Procedures

2.5 Study Suspension
The IACUC will review promptly all allegations of improper animal care and use at the
LSCDVAMC, and investigate the allegation if warranted. Allegations may be received by
the IACUC Chair, or brought to the IACUC Chair through individual IACUC members, the
ACOS/R or other members of the Research Service. Allegations may be received as an e-
mail or written correspondence. Allegations may be submitted anonymously, and forms for
this purpose are posted in the hallway outside of the Research Office.

2.5.1 Whistleblower policy
2.5.1.1 Purpose
This policy is intended to protect any individual who engages in good faith disclosure of
alleged wrongful conduct to a designated institutional official. Any communication that
proves to have been both unsubstantiated and made with malice or with knowledge of its
falsity is not protected by this policy. This policy is also intended to protect individuals against false allegations of wrongful misconduct. More specifically it:

- Encourages individuals to disclose wrongful conduct engaged in by others to the appropriate institutional official so that prompt, corrective action can be taken;
- Informs individuals how allegations of wrongful conduct can be disclosed;
- Protects individuals from reprisal by adverse employment action or other retaliation as a result of having disclosed wrongful conduct (individuals who self report their own misconduct are not afforded protection by this policy); and
- Provides individuals who believe they have been subject to reprisal or false allegations a fair process from these acts

2.5.1.2 Regulations

- **Acting in good faith** – anyone making a protected disclosure or filing a complaint concerning a violation or suspected violation of this policy must be acting in good faith and have reasonable grounds for believing the information disclosed indicates a violation of the policy.
- **False Allegation** – Any employee or volunteer who knowingly or with reckless disregard for the truth gives false information or knowingly makes a false report of wrongful conduct or a subsequent false report or retaliation will be subject to disciplinary action, up to and including termination. Allegations that are not substantiated yet are made in good faith are not subject to corrective action.
- **Retaliation** – No individual who makes a protected disclosure will suffer harassment, retaliation or adverse employment consequences. Any person who retaliates against any individual who makes a protected disclosure is subject to discipline up to and including termination. This policy is intended to encourage and enable employees and others to raise serious concerns within the institution prior to seeking resolution outside the institution.
- **Confidentiality** – Protected disclosures may be made on a confidential basis by the complainant or may be submitted anonymously to the Research Office, IACUC Coordinator and/or IACUC Chairperson. Protected disclosures and investigatory records will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation and in accordance with Records Retention Policy. All reports will be promptly investigated and appropriate corrective action will be taken if warranted by the investigation.

2.5.1.3 Process

- Complete a Cleveland VAMC Animal Incident Report which is located outside the main research office as well as in the Animal Facility. Submit the completed report to the IACUC Chairperson, Coordinator, compliance office or the main research office. This report is located in appendix 7.

2.5.2 Inquiry

The IACUC Chairperson will determine the degree of urgency and seriousness of the situation and initiate an inquiry. If there is any indication that there is a risk to animals’ health or well being, veterinary staff will be consulted in a timely fashion. Early in the course of documenting the allegation, the Chairperson will communicate with the PI.

After this initial inquiry, the circumstances surrounding the allegation will be presented at the next convened meeting of the IACUC. If the inquiry determines that the allegation was
inaccurate or without foundation, the allegation will be dismissed without any further action, and the IACUC will communicate this decision to the PI in writing. Otherwise, the IACUC will determine if the allegation is a major or minor compliance deficiency and if it was based on:
- a lack of education of the PI and/or study team,
- a deficient research management procedure,
- a willful disregard for animal subject protections, or
- some other factor.

If the inquiry determines that the allegation reflects a lack of education, the ARF Supervisor, Coordinator and/or Consulting Veterinarians will provide remedial instruction to the PI and study staff. The PI will indicate a plan of how to ensure continued education regarding best practices in research. These occurrences will be communicated to the IACUC, which will also consider whether a more general deficiency in training and/or education exists.

The IACUC may determine that additional information is required in order to understand the basis of the allegation. In that event, the IACUC will establish an ad hoc subcommittee to perform the investigation. The subcommittee may meet with laboratory personnel, ARF staff, and other individuals to obtain the information that is needed. The subcommittee will report back to the full IACUC at a convened meeting in a timely fashion.

The IACUC may determine that the allegation reflects a more serious concern and other sanctions are required. In that event the IACUC will notify the PI immediately.

2.5.3 Outcome
If the situation appears to be isolated, a miscommunication or misunderstanding or of a non-continuing nature, the issue will be resolved between the PI and the IACUC along with any further recommendations from the R&D Committee.

If the investigation indicates that continuing noncompliance, serious noncompliance or scientific misconduct has occurred, the IACUC is compelled to report the incident to outside authorities through the R&D Committee, ACOS/R, and Medical Center Director.

The IACUC must review and consider the PI's response to any corrective actions or steps to eliminate future occurrences.

All determinations and outcomes will be communicated to the R&D Committee in writing and to the CWRU IACUC if the noncompliance is associated with CWRU administered funding.

2.5.4 Suspension of a Protocol
The IACUC may suspend animal research activity if it determines that the activity is not being conducted in accordance with the ACORP provided by the PI and approved by the IACUC. It may also suspend any animal procedures not approved by the IACUC. The IACUC may suspend an activity only after review of the matter at a properly-convened IACUC meeting and if the vote for suspension is by a majority of a quorum. The Medical Center Director has the authority to suspend an ACORP prior to IACUC action.
The main categories of deficiencies that must be reported to outside authorities and the elements needed in the report are as follows:

- **Any serious or continuing non-compliance with PHS Policy (including any serious deviation or continuing non-compliance with the provisions of the “Guide”, as required by the PHS Policy) or United States Department of Agriculture USDA and AWAR.** The report will include:
  - When and how the IACUC became aware of the problem.
  - When the investigation was performed to determine facts and detail the circumstances that led to the non-compliance.
  - The results of that investigation, and
  - When the IACUC convened a quorum to suspend the activity.
  - What corrective actions the IACUC approved to stop the noncompliant activity and prevent future recurrences.

- **Suspension of previously approved protocols or procedures or studies that were never approved.** The report will include:
  - When and how the IACUC became aware of the problem.
  - When the investigation was performed to determine the facts and detail circumstances that lead to report of non-compliance.
  - The results of the investigation.
  - When the IACUC convened a quorum to suspend the activity.
  - What corrective actions the IACUC approved to prevent recurrences.

- **Failure to correct a significant deficiency, identified during a semi-annual IACUC program or facility self-assessment review.** The report will include:
  - The date when the IACUC identified the deficiency.
  - The timetable and plan approved for correction.
  - Why the correction(s) could not be completed according to the timetable.
  - The revised timetable.
  - The plan to finish the correction(s).

Although it is not considered an IACUC suspension, if VACO Office of Research & Development (ORD) places a veterinary hold on a protocol, it must be reported to other Federal agencies, if the IACUC and Medical Center Director find that information in the ACORP represents a reportable deficiency.

Deficiencies must be reported in writing within 5 business days through the ACOS/R and the Medical Center Director to the following agencies and offices:

- ORD (by contacting the Chief Veterinary Medical Officer’s (CVMO) office).
- Office of Laboratory Animal Welfare, as required by PHS Policy.
- The Animal Care Section at USDA Animal and Plant Health Inspection Service (APHIS), as required by AWAR, if the deficiency involves a species meeting the definition of an animal in the AWAR, or if the deficiency impacts the care or use of such a species.
- Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), as required by their rules of accreditation.
- CWRU IACUC, if the project involves animals purchased with funds awarded to CWRU.
- The VA Office of Research Oversight (ORO), as required by its policy.
- Any non-VA Federal agency funding an activity that has been suspended.
- The CWRU IACUC if the funding for the suspended activity is administered through CWRU.

If local efforts to correct deficiencies have proven inadequate, individuals may contact the CVMO directly to discuss concerns, solicit guidance, or seek information without requesting or receiving local permission to do so.

2.6 Conflict of Interest
As a public agency, the VA has an obligation to preserve public trust in the integrity and quality of research carried out by its investigators, among its patients, and in its facilities, and to exercise prudent stewardship of public resources, including public funds that support research programs. Appropriate mechanisms must be in place to ensure that actual or perceived financial conflicts of interest do not undermine that trust. With regard to conflicts of interest, all VA employees must comply with the criminal statute pertaining to acts affecting personal or imputed financial interest (18 U.S.C. Section 208) and the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635). VA Regional Counsel is authorized to interpret these provisions.

2.6.1 IACUC Member Conflicts
The IACUC is responsible for ensuring that the protocol review process is not compromised by conflicts of interest arising from members participating in animal research reviewed by the IACUC. Therefore, no IACUC member may participate in the IACUC review, or in the approval of a research project in which the member is either personally involved in the project, and/or has a financial conflict, except to provide information requested by the IACUC. Voting members who have conflicts of interest are required to recuse themselves from deliberations and are not counted toward the quorum for that specific protocol.

2.6.2 Investigator Conflicts
Each PI, co-investigator, consultant and collaborator will submit a DVA Research and Development Conflicts of Interest Form VA 10-1313-9 for all projects submitted for review by the IACUC. Use of the information on the survey is for the review and approval of this proposed research project only. An updated version of this form is required for annual renewal of a project and is located in appendix 2.

2.6.3 Non-Voting Member Conflicts
The ACOS/R may not serve as a voting member on the IACUC, and when in attendance, needs to be very sensitive to the occurrence or appearance of conflict of interest relative to his/her supervisory, managerial, or fiscal authority. The ACOS/R should avoid intervention or participation in deliberations involving entities in which he/she has financial or economic interests, except to provide information as requested by the IACUC. Any non-voting attendee of an IACUC meeting should leave the room when in conflict with an issue under consideration.
3 SURVIVAL SURGERY

3.1 Training for Surgery
The use of animals for surgical training and demonstration and for the development of new surgical procedures may be necessary in those circumstances where it can be demonstrated that a suitable alternative is not available. This applies to surgeons, associated personnel and any individuals planning to undertake surgical training or demonstration of new techniques in animal models, or who are engaged in the development or further development of new techniques.

- Prior to the commencement of any training sessions, the PI must have IACUC approval for the ACORP in which the surgery is described.
- All participants must be informed of, and fully understand, their ethical and legal responsibilities regarding the use of live animals. They should also be informed of their right to report incidents of incompetence, misconduct or other breaches of policy.
- Training methods which do not need animals must be used wherever possible. Training in basic surgical skills such as suturing, knot tying and the anastomosis of hollow viscera and blood vessels can, to a large extent, be performed on non-living material, and most other skills can be learned directly from more experienced surgeons.
- The PI must ensure that the welfare of the animals will be considered at all times; before, during and after procedures. This includes provision of appropriate holding facilities, food and water, minimization of pain and distress and euthanasia.
- The PI must ensure that there are enough trained personnel to provide proper monitoring of all the animals during the procedure and proper care of the animals before and after the procedure.
- The PI should carefully evaluate the benefits of holding surgical workshops sponsored by a commercial organization where animals are required for the demonstration of new equipment. Workshops should not be held by commercial operators purely for promotional or commercial reasons. Animals should only be used where the new techniques or equipment to be demonstrated are likely to lead to significant benefits in human or animal surgery.
- If the animal is to be killed, it must be killed using an AVMA approved method.
- Proposals for surgeons to perform the same procedure repeatedly on anaesthetized animals in a single workshop may be approved provided anesthesia and analgesia are maintained and the animals are euthanized at completion of the workshop.

3.2 Location of Surgery
The IACUC must approve all areas where surgical procedures will be conducted on live animals before they can be activated. The requirements for these areas will differ based on the type of procedures that will be conducted and the animal models.

3.2.1 Major Survival Surgery on Mammals other than Rodents must be conducted in a dedicated facility specifically intended and used only for that purpose and which is maintained and operated to ensure cleanliness. Aseptic procedures, including the use of sterile draping and the wearing of sterile surgical gloves, gowns, caps and face masks, must be used. Surgical instruments must be sterilized.

3.2.2 Major Survival Surgery on Rodents does not require a dedicated surgical facility. The area of the laboratory or room where surgery is performed should not be used for other
functions at the time that surgery is in progress and should be clean and free of clutter. Procedures must minimally include the use of sterile instruments, surgical masks and gloves, surgical draping or the use of a “no touch” surgical technique, and aseptic preparation of the surgery site.

3.2.3 Non-Survival Surgery is defined as a surgery in which the animal is euthanized before recovery from anesthesia. Non-survival surgery does not require a dedicated surgical facility. The area of the laboratory or room where surgery is performed should not be used for other functions at the time that surgery is in progress and should be clean and free of clutter. Procedures must ensure that the animal subject does not recover from anesthesia, and animals must be maintained at an anesthetic plane which precludes pain and distress without recovery until the time of euthanasia.

3.3 Survival Surgery Procedures
3.3.1 Pre-Surgery. The protocol must describe procedures used to prepare an animal for surgery. These procedures may include aseptic preparation of the surgical site (e.g., shaving of fur, skin disinfection), pre-surgical medication(s), and food or fluid restriction. The IACUC, along with the Attending Veterinarian, has the responsibility for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures to be performed.

3.3.2 Post-Surgical Documentation. The post-surgical period is generally considered to be the period from the end of surgery to the point when the surgical wound is healed (e.g., time of suture removal). The period may be extended in cases where a physical impairment has been induced or a catheter or device exits from the body despite healed surgical wounds. During the post-surgical period, animals must be observed on a defined schedule by qualified personnel and the observations recorded in the animal record. For rats and mice, this requirement will be satisfied by the use of a post-operative card (‘blue surgery card’), placed behind the cage card of the animal(s) involved. For other mammalian species, all post-surgical notes must be placed in the individual animal record.

3.3.3 Multiple Survival Surgery
Multiple major survival surgeries may be permitted if scientifically justified by the user and approved by the IACUC. If multiple major survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

Justification for multiple survival surgery protocols includes:
- A description of how the second surgery relates to the research protocol;
- The interval between surgeries;
- An explanation for not conducting multiple procedures in one surgical session;
- A description of the additional follow-up observation that will be conducted, beyond what is typically required for standard single survival surgeries. This observation should include an awareness of the second surgery during the pre-surgical, the surgery and the post-surgical periods. Description of follow-up should also include any special procedures or extra care required during the period between surgeries as well as a list of post-operative criteria that would exclude or delay the subsequent surgery.
4 Monitoring the Care and Use of Animals

4.1 Semi-Annual Program and Facility Self-Assessment Reviews

According to the USDA Animal Welfare Act Regulations and Standards (see 9 C.F.R. §2.31(c)(1)) and PHS Policy, the IACUC must perform a self-assessment review of the program of animal care and research use, and an inspection of the animal facilities, husbandry practices, and laboratories where animal procedures are performed. This review must be repeated at least every 6 months. This self-assessment review must be conducted using the standards established in the most current Guide (see “Institutional Animal Care and Use Committees”), PHS Policy (see Sec. IV.B), the Animal Welfare Act (see 7 U.S.C. §2143[b][3] and [b][4]), USDA AWAR (see 9 C.F.R. §2.31[c][2]).

- The semi-annual facility and program review is placed in the agenda by the IACUC Coordinator.
- Prior to the convened meeting, the Semi-Annual Self-Review Forms are distributed to all Committee members.
- The programmatic component of the review is conducted and the members indicate their assessment of each item as it is read. The collective input from all voting members present is collated into a single form.
- At least 2 voting members of IACUC must conduct the facility inspection.
- The semi-annual program and facility review are discussed at the next scheduled IACUC meeting.
- A timetable for corrective action is established and documented. A majority of all voting IACUC members must approve the report at this meeting.
- A signed copy of the complete report (including Forms 1, 2, 3) is sent through the ACOS/R and Medical Center Director to the CVMO within 60 days of the self-assessment.
- A copy of the report is submitted to the R&D Committee for review. R&D approval is not required before submission of the final document to the CVMO.
- The original signed complete report must be retained in accordance with the records retention policy.
- The report is located in appendix 8.

4.2 Post Approval Monitoring

Continuing IACUC oversight of animal activities is required by federal laws, regulations and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Post-approval monitoring (PAM) is considered here in the broadest sense, consisting of all potential types of protocol monitoring following initial protocol approval by the IACUC. PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. Methods include continuing protocol review; laboratory inspections (as part of regular facilities inspections or conducted separately); veterinary or IACUC observation of select procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments. The IACUC, veterinary, animal care and compliance staff may all conduct PAM, which may also be used as an educational tool.

4.3 Physical Restraint

Restraint is the use of manual, mechanical, or chemical means to limit some or all of an animal's normal movement for such purposes as examination, collection of samples, and
drug administration. Typically, animals are restrained for brief periods, usually seconds or minutes, in most research applications.

4.3.1 Prolonged Restraint
Prolonged restraint (usually fifteen minutes or longer. Restraint may involve confining animals in spaces smaller than mandated space requirements or tethering and should be avoided unless it is essential for achieving research objectives. In order to approve animal procedures involving prolonged restraint, the IACUC must receive a scientific justification for the use of restraint and a detailed description of the restraint device to be used. This description should include dimensions, acclimatization procedures including environmental monitoring, and length of restraint. This information is presented to the IACUC during the ACORP review process. The IACUC will review this information to determine whether the restraint meets standards of the Guide. If standards are not met, the investigator must provide justification before approval is granted. As with all ACORP reviews, consideration is given to whether the potential pain and distress to the animal subjects is outweighed by the potential scientific gain of the research.

4.4 Food or Fluid Restrictions
Restriction is typically measured as a percentage of the ad libitum or normal daily intake or as percentage change in an animal’s body weight. In order to approve animal procedures involving food and/or fluid restriction, the IACUC must receive a scientific justification for such restriction, as well as a detailed description of the monitoring methods and schedules that will be established to check for excessive weight loss.

- The least restriction that will achieve the scientific objective should be used. In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcement, instead of restriction, is recommended.
- When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid must be available to provide for development of young animals and to maintain long-term well-being of all animals.
- When only fluid restriction is used, special attention must be given to ensure that animals consume a suitably balanced diet because food consumption might decrease with fluid restriction.
- Experimental procedures utilizing food or water restriction must include a program for daily monitoring of physiologic and behavioral indexes. Body weight is recorded at least once per week or more often, as might be needed for small animals, such as rodents. A daily log sheet is maintained, and kept with the animals, with the following information:
  o Record of food/water schedule
  o Health status of the animals
  o Any adverse events
  o Criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol must be defined.
5 Occupational Health and Safety of Personnel
The Occupational Health and Safety Program (OHSP) is an important program designed to protect both personnel and animals. The occupational health program for animal care personnel or persons using animals is provided by the IACUC in conjunction with Personnel Health (PH). All research personnel working with animals or animal tissue have an annual allergy screening by Personnel Health (PH). Occupational Health coverage also extends to non VA personnel while working on VA premises.

5.1 Occupational Health Screening Procedures
- Any persons newly hired or added to an ACORP must complete the Personnel Health Laboratory Animal Allergy Questionnaire Initial form (Appendix 9). Also, if a person’s medical conditions change in the course of the year, the form should be updated at the time of change.
- PH will review the health evaluations
- PH maintains records for each research and animal care staff member.
- Personnel working with animals are responsible for completing the annual Personnel Health Laboratory Animal Allergy Questionnaire – Follow up form (Appendix 10) through PH.
- Personnel that are enrolled in the CWRU Occupational Health and Safety Program must complete the Laboratory Animal Allergy Questionnaire. PH will verify with CWRU that in fact the individual is enrolled in CWRU’s Occupational Health and Safety program and will document this in the shared PH and Research database.

5.2 Occupational Safety
Personnel safety is an important objective of LSCDVAMC. Safety is promoted and achieved through good facilities, proper maintenance and calibration of safety equipment, the establishment and enforcement of safety rules, informed and trained personnel, and the use of appropriate protective clothing and equipment. In general, health and safety matters are related to facility and equipment design, the species one works with, the frequency and type of contact, and one’s own health status. The Safety Research Coordinator is responsible for administering the New Employee Safety Orientation and annual Safety Orientation.

5.3 Special Susceptibilities
Persons who are or are planning to become pregnant, are immunocompromised for any reason (AIDS, chemotherapy, steroid use, chronic disease), have neuromuscular or musculoskeletal problems, have diabetes, or have other illness that may place them at extra risk, should contact PH before using animals.

5.4 Personal Hygiene
- Animal care and use personnel shall wear a full-length uniform or lab coat and, as appropriate, a face mask, gloves, and head or hair cover in animal holding rooms while opening cages and handling animals. These will not be worn in public areas and never be taken home.
- Whenever bare hands, arms, neck/face, or head become accidentally or unavoidably contaminated with animal blood, urine, feces, or hair, such contamination should be removed as soon as possible by washing thoroughly with water and soap. When materials enter the mouth or eyes, wash the exposed area with generous amounts of water. Report the incident to PH for further evaluation.
- Projects involving hazardous agents or materials have very strict requirements for clothing and procedures. Containment procedures are for the protection of personnel and other animals. Specific standard hazard signs operating procedures should be posted only when hazardous agents are in use.
- Signs no longer relevant must be removed.

5.5 Required Safety Equipment
To safeguard both research personnel and laboratory animals, the Occupational Health and Safety Program requires that all personnel with direct animal contact use the following personal protective equipment (PPE).
- Surgical scrubs and/or a laboratory coat at all times.
- Gloves
- Eye and Face Protection as needed
- Additional safety equipment may be required dependent on study design.

5.6 Animal Bite and/or Scratch Procedure
- All bite or scratch wounds that result in bleeding should be scrubbed and cleansed immediately and thoroughly with soap and water. Injuries sustained from a cat or dog should be washed for 15 minutes. First aid kits are available in the technician’s office. All bite and scratch wounds should be observed closely. All skin penetrating injuries must be reported to Personnel Health. If redness, pain, or swellings occur around the wound, a PH physician should be consulted.
- The employee must inform his or her supervisor of the injury as soon as possible after initial first aid is completed. A record of the injury should be noted with the main Research Office. The laboratory worker should then be referred to Personnel Health for evaluation and treatment.
- A tetanus immunization should be current (within 10 years). If the laboratory worker’s tetanus vaccination program is not current, he or she will receive a tetanus immunization.
  - Dog and cat bite incidents require that the animal be quarantined for 10 days. Other bites by animals with undefined pathogen status may also require quarantine and additional testing.

5.7 Animal Biosafety Level 2 (ABSL-2)
5.7.1 Purpose
To establish a policy that outlines the requirements for establishment and operation of an animal Biosafety level 2 (ABSL-2) room in the Wade Park ARF.

5.7.2 Policy
Animal Biosafety Level 2 is suitable for work involving laboratory animals infected with agents associated with human and animal disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 requires that
  - access to the animal facility is restricted;
  - personnel must have specific training in animal facility procedures, the handling of infected animals and the manipulation of pathogenic agents;
  - personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations and husbandry procedures; and
- procedures involving the manipulation of infectious materials, or where aerosols or splashes may be created, should be conducted in biosafety cabinet or by use of other physical containment equipment. Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Tack mat will remain installed in front of the designated Biosafety Level 2 room and changed weekly.

5.7.3 Procedure
All personnel working in an ABSL-2 area will practice the following:
- Laboratory personnel will have specific training in handling the pathogenic agent(s) they are working with.
- Laboratory personnel will receive appropriate immunizations or tests for any agents handled or potentially present in the room (serum may be collected).
- Access is limited were the work is to be conducted.
- Extreme precautions must be taken with contaminated sharp items. Use alternatives to sharps wherever possible.
- Procedures are conducted in a class 2 biological safety cabinet provided in the room, and where aerosols or splashes may occur, face shields will also be worn.
- ARF Training Procedures
  - Personnel must be on an approved ACORP and have received all animal and safety training.
  - Personnel must have read and fully understand your protocol and be aware of the potential hazards of the pathogens they are working with.

5.7.3.1 Entry Procedures
- Prior to entering the ABSL-2 room, put on shoe covers a surgical gown (tied in the back), gloves, goggles, a disposable mask and a surgical cap.
- Step into the ABSL-2 housing room.
- **Conducting Your Procedures**
  - Always work with infectious agents in the class 2 biological safety cabinet.
  - Always spray and wipe down all interior surfaces of the class 2 biological safety cabinet with Clidox, before and after working. Do not spray the top grille of the class 2 biological safety cabinets (this is where the filter is located).
  - Always open rodent micro-isolator cages in the class 2 biological safety cabinet with aseptic micro-isolator technique (If you have not had this training, contact the attending veterinarian).
  - When infecting animals with pathogenic agents described in your IACUC approved protocol, you must place a Biohazard label on the door to the room the biohazard hood and in front of cage cards of cages holding infected animals. The identity of the pathogen, date infected and dose per animal must be written on the biohazard label affixed to the cage.
- The biohazard sign on the door of the room and in front of animal cage cards will include the following information:
  - PI Name:
  - Phone Number:
  - Protocol Number:
  - Pathogenic agent:
  - Husbandry by: PI or ARF (circle)
- The ARF or investigative staff by mutual agreement is responsible for routine husbandry in the ABSL-2 room. If you need to make additional cage changes, make sure to follow the appropriate guidelines.
- Infected bedding or carcasses which require incineration prior to disposal, must be placed in a biohazard barrel. The barrels are located in the room.
- Cages that had infected bedding or animals and which require incineration prior to disposal, must be placed in a second, labeled, biohazard barrel. The barrels are located in the room.
- Upon completion of your work in the ABSL-2 room, all infected caging and carcasses will be placed in the appropriate red biohazard barrels, sharps will be placed in the sharps container and contaminated non-sharps such as gloves placed into the hazardous waste container all of which are located in the animal housing area. The ARF will process and dispose of the materials for you.
- If you no longer need cages with *non-infected* animals, no special handling is required; you may take them to the dirty side of the cage washing room.
- Always place contaminated sharps in the approved biohazard container.
- Report all spills and accidents that result in overt exposure to infectious materials to the VA Safety Coordinator. Spray and wipe down all interior surfaces of the class 2 biological safety cabinet and all other work surfaces with Clidox after working.

### 5.7.3.2 Exiting Procedures

- When all of your work is completed, your animal cages are back on the housing rack, your infectious waste has been placed in the appropriate red biohazard barrels and the class 2 biological safety cabinet and all other work spaces have been decontaminated with Clidox, you may remove your gloves, and dispose of them in the biohazard waste container provided. *Do not touch any surfaces in the housing area.* Proceed to the exit area.
- Remove mask, cap, gloves and shoe covers and discard them in the biohazard trash can, provided in this area. Place the gown and goggles in an autoclavable bag for decontamination prior to washing. Wash hands in sink prior to exiting the room.
- Do not exit the room with the personal protective outerwear that was donned immediately prior to entering the room; these items must stay in the room to be disposed of by the ARF.
- After exiting the room wash hands AGAIN in the nearest available sink.
6 Animal Environments, Housing and Management

The environment, housing and management are provided in accordance with The Guide for the Care and Use of Laboratory Animals (2010, “The Guide”) and in compliance with applicable federal, state, and local laws and regulations, such as the federal Animal Welfare Regulations, or AWRs (CFR 1985), and Public Health Service Policy on Humane Care and Use of Laboratory Animals, or PHS Policy (PHS 2002). Justification and additional details regarding the housing, space, illumination and ventilation within the animal facilities are provided in The Guide.

6.1 Physical Environment

6.1.1 Housing

Primary enclosures which provide the limits of an animal’s immediate environment must:

- Allow for the normal physiologic and behavioral needs of the animals, including urination and defecation, maintenance of body temperature, normal movement and postural adjustments, and, where indicated, reproduction.
- Allow species specific social interaction and development of hierarchies within or between enclosures.
- Make it possible for the animals to remain clean and dry (as consistent with the requirements of the species).
- Allow adequate ventilation.
- Allow the animals access to food and water and permit easy filling, refilling, changing, servicing, and cleaning of food and water utensils.
- Provide a secure environment that does not allow escape of or accidental entrapment of animals or their appendages between opposing surfaces or by structural openings.
- Are free of sharp edges or projections that could cause injury to the animals.
- Allow observation of the animals with minimal disturbance of them.

6.1.2 Animal Space Recommendations

Recommended space requirements are:

<table>
<thead>
<tr>
<th>Animals</th>
<th>Weight</th>
<th>Floor Area/Animal</th>
<th>Height(^{a}) in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mice</td>
<td>&lt;10g</td>
<td>6 in(^{2})</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Up to 15g</td>
<td>8 in(^{2})</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Up to 25g</td>
<td>12 in(^{2})</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>&gt;25g</td>
<td>&gt;15 in(^{2})</td>
<td>5</td>
</tr>
<tr>
<td>Mouse – Female and Litter (group)(^{c})</td>
<td></td>
<td>51 in(^{2})</td>
<td>5</td>
</tr>
<tr>
<td>Rats</td>
<td>&lt;100g</td>
<td>17 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Up to 200g</td>
<td>23 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Up to 300g</td>
<td>29 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Up to 400g</td>
<td>40 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Up to 500g</td>
<td>60 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>&gt;500g(^{b})</td>
<td>&gt;70 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td>Rat – Female and Litter (group)(^{c})</td>
<td></td>
<td>124 in(^{2})</td>
<td>7</td>
</tr>
<tr>
<td>Rabbits</td>
<td>&lt;2 kg</td>
<td>1.5 ft(^{2})</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Up to 4 kg</td>
<td>3.0 ft(^{2})</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Up to 5.4 kg</td>
<td>4.0 ft(^{2})</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>&gt;5.4 kg(^{b})</td>
<td>&gt;5.0 ft(^{2})</td>
<td>16</td>
</tr>
<tr>
<td>Cats</td>
<td>≤4 kg</td>
<td>3.0ft(^{2})</td>
<td>24</td>
</tr>
</tbody>
</table>

\(^{a}\) Height for animals is measured after maximum growth but before senility.

\(^{b}\) Consult Guide for specific height recommendations for large mammals.

\(^{c}\) Litter size recommendations are based on the size of the cage and the number of animals housed.
<table>
<thead>
<tr>
<th>Weight Range</th>
<th>Space Requirement</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥4 kg (^b)</td>
<td>≥4.0 ft(^2)</td>
<td>24</td>
</tr>
<tr>
<td>&lt;15 kg</td>
<td>8.0 ft(^2)</td>
<td>NA</td>
</tr>
<tr>
<td>Up to 30</td>
<td>12.0 ft(^2)</td>
<td>NA</td>
</tr>
<tr>
<td>&gt;30 kg (^b)</td>
<td>≥24</td>
<td>NA</td>
</tr>
</tbody>
</table>

\(^a\)From cage floor to cage top.
\(^b\)Larger animals might require more space to meet the performance standards.
\(^c\)Other breeding configurations may require more space and will depend on considerations such as number of adults and litters and size and age of litters. Other considerations may include culling or litters or separation of litters from the breeding group.

Space allocations may be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese animals, and group or individual housing).

### 6.1.3 Temperature and Humidity

The recommended dry-bulb temperatures for laboratory animals are:

**Dry-Bulb Temperature**

<table>
<thead>
<tr>
<th>Animal</th>
<th>°C</th>
<th>°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse, rat</td>
<td>20-26</td>
<td>68-79</td>
</tr>
<tr>
<td>Rabbit</td>
<td>16-22</td>
<td>61-72</td>
</tr>
<tr>
<td>Cat, Dog</td>
<td>18-29</td>
<td>64-84</td>
</tr>
</tbody>
</table>

Relative humidity will be controlled, within the range of 30 to 70%.

Environmental temperatures will be adjusted as necessary under specific conditions, such as postoperative recovery, housing of some hairless rodents, and housing of neonates that have been separated from their mothers.

### 6.1.4 Ventilation

The purposes of ventilation are to supply adequate oxygen; remove thermal loads caused by animal respiration, lights, and equipment; dilute gaseous and particulate contaminants; adjust the moisture content of room air; and, where appropriate, create static-pressure differentials between adjoining spaces.

The acceptable general standard for secondary enclosures is a minimum of 10-15 fresh-air changes per hour.

If the specialized enclosures contain adequate particulate and gaseous filtration to address contamination risks, recycled air may be used in the secondary enclosures. Filtered isolation caging without forced ventilation, husbandry practices-including sanitation, placement of cages in the secondary enclosure, and cage densities-are adjusted to improve the microenvironment and heat dissipation.

The use of non-recycled air is preferred for ventilation of animal use and in holding areas.
6.1.4.2 Maintenance and Monitoring
HVAC function at the level of the secondary enclosure by measuring supply- and exhaust-air volumes, as well as static-pressure differentials, where applicable, will be measured semi-annually or soon after the changes to HVAC function. Results will be presented to IACUC on the semi-annual inspection report.

6.1.5 Illumination
A time-controlled lighting system should be used to ensure a regular diurnal cycle, and timer performance should be checked periodically to ensure proper cycling. Light at the cage level should be between 130 and 325 lux. Management practices, such as rotating cage position relative to the light source or providing animals with ways to modify their own light exposure by behavioral means (e.g., via tunneling or hiding in a structure), are used to reduce inappropriate light stimulation of animals. Albino animals are not housed on the top shelf of racks to reduce their risk of phototoxic retinopathy.

6.1.6 Noise
Noisy animals—such as dogs—are housed away from quieter animals, such as rodents and rabbits. Activities that might be noisy are conducted in rooms or areas separate from those used for animal housing. Personnel are trained in alternatives to practices that produce noise. Environmental noise is reduced by the use of cushioned casters and bumpers on carts, trucks, and racks. Radios, alarms, and other sound generators are not to be used in animal rooms unless they are part of an approved protocol or an enrichment program.

6.1.7 Power
The electrical system should be safe and provide a sufficient number of power outlets and suitable amperage for specialized equipment. In the event of a power failure, an alternative or emergency power supply is available to maintain critical services (e.g., HVAC) or support functions (e.g., freezers) in animal rooms, surgical suites, and other essential areas. Uninterrupted power (red outlet) is outfitted for moveable yet essential equipment (lighting monitoring and/or control system).

6.1.8 Transport through Corridors to Lab Spaces within VA
Animals being transported outside of the animal research facilities should have their cages draped to prevent view and excess distress to the animal.

6.1.9 Security in the Animal Research Facility
The Animal Research Facility is a restricted area and only authorized personnel are allowed into the facility. Doors to the facility are kept closed at all times and proximity key card access is required to enter. Personnel may only obtain key card access to this space once the appropriate procedures, trainings and approvals have been secured.

6.2 Behavioral Management
6.2.1 Structural Environment
The structural environment, when indicated, will include equipment that increases opportunities for the expression of species-typical postures and activities and enhances the animals’ well-being.

Depending on the animal species and use, the structural environment may consist of components of the primary enclosure, e.g. resting boards, shelves or perches, equipment
for environmental enrichment or objects for manipulation by the animals, e.g. toys, foraging devices, nesting materials, and cage complexities, e.g. tunnels, and swings.

### 6.2.2 Social Environment

The social environment usually involves physical contact and communication among members of the same species (co-specifics), although it can include noncontact communication among individuals through visual, auditory, and olfactory signals.

Social animals are housed in physical contact with co-specifics. However, experimental, health, and behavioral reasons might preclude this kind of housing.

The use of solitary housing of social animals must be scientifically justified. When they must be housed alone, other forms of enrichment are provided to compensate for the absence of other animals, such as safe and positive interaction with the care staff and enrichment of the structural environment.

### 6.2.3 Activity

Animals have opportunities to exhibit species-typical activity patterns. Forced activity for reasons other than attempts to meet therapeutic or approved protocol objectives is to be avoided. In most species, physical activity that is repetitive, is non-goal-oriented, and excludes other behavior is considered undesirable.

### 6.3 General Animal Facility Husbandry

All aspects of animal husbandry are conducted according to "The Guide" and within the norms of good veterinary care practices. In general all animals are provided with a clean, safe environment.

#### 6.3.1 Food

All animal feed is ordered from authorized national vendors. All feed is inspected upon arrival and all damaged/contaminated bags/bulk feed is rejected. All stock is rotated on a first in, first out basis and stored on an elevated surface and at least six inches away from the wall. In dog and cat rooms, food is stored in mobile 35-gallon Rubber Maid containers with lids.

#### 6.3.2 Water

All water originates from city water lines and is fit for human consumption.

Rodents are given water in water bottles with sipper tubes. Cagewashed and autoclaved replacement water bottles and sipper tubes are given each week to rodents based in Wade Park.

Cats are given water bowls which are rinsed and refilled daily and cagewashed weekly.

Dogs housed in the dog runs are on an automatic watering system (Edstrom). Dogs are monitored to assure that they can and do use the watering devices. Dogs in individual cages are given water in bowls which are rinsed and refilled daily and cagewashed weekly.
Investigators may provide water with special additives per IACUC approved protocol. The investigators are responsible for maintaining a supply of the water in the ARF. If necessary they must also provide special instructions for its use to the animal technicians.

### 6.3.3 Bedding
Aspen shavings and Corncob bedding and Nestlets are sterilized and used for all rodents housed in microisolator cages. Aspen shavings and Corncob bedding are stored on pallets away from the wall and open bags are stored in plastic containers with lids.

Bedding shipments are inspected upon arrival and any torn or wet bags are returned to the vendor. Upon opening of the bags, the bedding is visually inspected for contamination. Any abnormalities in the condition of the bedding are reported to the vendor. Bedding is stored on an elevated surface at least six inches away from the wall.

### 6.3.4 Sanitation
No litter is used for dogs housed in cages or runs. All rodent cages are changed at least weekly or on an as needed basis depending on the number of animals in the cage, litters, condition of the animal, etc. Diabetic rodents are changed every other day or even daily depending on the number of animals in the cage. Dirty rodent cages are emptied into the Allentown bedding disposal unit. Cat litter boxes are scooped daily and washed twice a week.

<table>
<thead>
<tr>
<th>Enclosure</th>
<th>Frequency</th>
<th>Method</th>
<th>Cleaning agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid bottom rodent cages</td>
<td>Once / week</td>
<td>Cage Washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Cage lids / filter tops; wire bars</td>
<td>Biweekly</td>
<td>Cage Washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Rodent cage racks and shelves</td>
<td>Weekly</td>
<td>Hand washed</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Biweekly</td>
<td>Cage washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Water bottles/ sipper tubes</td>
<td>Bottle washer</td>
<td>Bottle washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Dog – pens/runs and equipment</td>
<td>Floors - daily</td>
<td>Swept/mopped</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Walls - monthly</td>
<td>Lifegard 256 Plus via pressure sprayer followed by thorough rinsing</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Enrichment equipment washed biweekly</td>
<td>Cage Washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Cat - group housing room and equipment</td>
<td>Floors - daily</td>
<td>Swept/mopped</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Enrichment equipment washed biweekly</td>
<td>Cage washer</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Walls washed monthly</td>
<td>Hand washed</td>
<td>Lifegard 256 Plus with water</td>
</tr>
<tr>
<td>Rodent housing rooms</td>
<td>Enrichment Equipment - Weekly to biweekly</td>
<td>Cage washer, bottle washer, autoclave</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Floors – Daily</td>
<td>Swept/mopped</td>
<td>Lifegard 256 Plus</td>
</tr>
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<td></td>
</tr>
<tr>
<td>Walls – Semi-Annually</td>
<td>Hand washed</td>
<td>Lifegard 256 Plus with water</td>
<td></td>
</tr>
<tr>
<td>Support areas – Cage Washer, Bottle Washer, Necropsy, Store rooms, office, &amp; corridors</td>
<td>Floors - Daily</td>
<td>Swept/Mopped</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td></td>
<td>Walls – Semi-Annually</td>
<td>Hand washed</td>
<td>Lifegard 256 Plus</td>
</tr>
<tr>
<td>Mops/Buckets</td>
<td>Mops – daily</td>
<td>Laundered by EMS</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Buckets – weekly</td>
<td>Cage washer</td>
<td>Lifegard 256 Plus</td>
</tr>
</tbody>
</table>

6.3.4.1. Diagnostic Sanitation Program
Temperatures in the cage, rack and bottle washers are monitored and charted weekly using Temp-Tape by Pharmacal. The temperature gauge is also checked on a daily basis. Post sanitation cage, bottle, and sipper tube cultures are completed on a quarterly basis and if a problem is found, it is addressed immediately. Sentinel animals are also housed in each room and tested for various bacteria. Quarterly bacteriological culture reports are reviewed at the IACUC meeting.

6.3.5 Waste Disposal
6.3.5.1 Disposal of Soiled Bedding & Refuse
Noninfectious soiled bedding is bagged and discarded in the medical center dumpster. Other refuse such as shipping cages, paper, and plastic waste are carted to the medical center dumpster at least once per day.

6.3.5.2 Disposal of Carcasses
Carcasses are double bagged in plastic biohazard bags and stored in the cold room red bins that are picked up by Stericycle, Inc. and transported to an incinerator facility.

6.3.5.3 Disposal of Hazardous Wastes
6.3.5.3.1 Infectious Waste
Some animals are infected with Vancomycin Resistant Enterococci, other Enterococci, *Klebsiella pneumoniae*, *Candida galabrata*, *Bacterioides fragilis*, which are Class I pathogens, or *Staphylococcus aureus*, a Class 2 pathogen. These animals are housed separately from the rest of the population and handled using BSL-2 guidelines:
- The investigative team provides all husbandry and collects waste. Soiled bedding is placed in red BIOHAZARD-labeled plastic barrels that have been lined with a red biohazard plastic bag. The barrels are then transported to the warehouse dock and treated in the Sani-Pak. Bedding is changed twice/week.
- Caging is rinsed with Germ-o-Solv before it is transported to the cage washer for washing.
- Animal carcasses are placed in plastic biohazard bags and stored in the cold room until Stericycle, Inc. removes them for incineration.

6.3.5.3.2 Toxic Agents
Handling, bagging, storage, and disposal depend upon the agent being used. The use of toxic agents required approval from the Subcommittee on Research Safety. Toxic agents in current use at the LSCDVAMC include the following:
**Streptozocin:** Streptozocin (STZ) has been reported to be a carcinogen and experimental teratogen in rodents. Tumors usually do not appear prior to 6 to 12 months and do not appear in all animals. STZ bio-accumulates in the liver, kidney and pancreas. 10-20% of STZ is excreted unmetabolized. However, 60-70% of STZ is metabolized within 4 hours. STZ decomposes to diazomethane when exposed to alkaline pH. Diazomethane is acutely toxic and is an inhalation hazard. Disinfectants with alkaline pH such as bleach and quaternary ammonium compounds cannot be used to clean up STZ contaminated materials/areas. Virkon S is a broad range disinfectant effective against resistant organisms such as adenovirus and is acidic.

Appropriate PPE such as gloves, lab coat and mask will be worn when handling STZ exposed animals, tissues, bedding etc. Aerosol generating activities involving STZ (e.g. prep stock of solutions, administration, necropsy, cage changes) will be performed in containment (fume hood). Waste will be disposed of in yellow containers which are contracted through Stericycle for trace chemo waste. During the inoculation period, cages containing these animals will be labeled with a hazard cage card to be placed in front of the normal cage card until contaminated bedding has been collected and animals are placed in a clean cage. Contaminated cages will be cleaned with Clidox before their return to the ARF and any remaining bedding sticking to the cage will be removed with a paper towel and both will be disposed of in the yellow containers. The RSC/CHO will be contacted regarding disposal of unused chemical.

**Conotoxins** (select agent toxin) and **Bungarotoxin** are used only in exempt quantities in the investigator’s laboratory during terminal experiments on anesthetized mice. Bungarotoxin (1 nM in 0.5 ml) or contoxins (up to 200 nM in 0.5 ml) is given as a single bolus injection into the peritoneum. At the end of the experiment, the mice are euthanized and their carcasses are double-bagged and placed in the cold room for subsequent removal by Stericycle, Inc.

**6.3.5.3.3. Radioisotopes**
- Short and long half-life solid radioactive waste. Upon arrival of the radioisotope to the facility, someone from radiation safety picks up the material and transports it to a marked radioactive freezer. The researcher arranges to have the radioactive substance transported to his/her lab for use. Once the researcher has completed the experiments, waste is handled and bagged by research technicians, stored in the animal room in an appropriately labeled radioactive waste receptacle, transferred to the RSO, and shipped out monthly for disposal.
- Biological radioactive wastes and fluids. Daily disposal via the sanitary sewage system by research technicians unless otherwise directed in writing by the RSO.
- Non-regulated animal carcasses (<0.05 mCi of 3H or 14C/g of tissue averaged over the entire weight of the carcass or tissue sample). Carcasses are handled and bagged by research technicians and stored in the laboratory in appropriately labeled refrigerators/freezers until transferred to the RSO. They are packed in RADIOACTIVE HAZARD-labeled containers and picked up by Stericycle, Inc.
- Radioactive animal carcasses are handled in the same way, with the exception that the carcasses are shipped out by the RSO for disposal as radioactive waste.
- Cages are prewashed with Count-Off by a member of the investigative team before being placed in the cage washer. The RSO performs random wipe tests on the caging and the cage washer.
6.3.6 Pest Control
EMS provides pest control through the use of an authorized pest control contractor which provides service on an as needed basis. No treatment is performed without verification of an infestation by the authorized pest control contractor. All treatments are coordinated with staff (investigators, technicians, the ARF supervisor, and animal technicians).

6.3.7 Emergency, Weekend, and Holiday Care
Animals are cared for by qualified personnel every day, including holidays and weekends, both to safeguard their well being and to satisfy research requirements. Any unusual problems (e.g. illness, infections, injuries, deaths, etc) are brought to the attention of the Consulting Veterinarians, the PI, and ARF Supervisor. If the illness or injury is severe enough, the animal is humanely euthanized.

During emergency situations, Medical Center Police will make frequent tours through the ARF to assure that essential services are being provided for the animals. If emergencies occur outside of working hours, Boiler Plant personnel will be contacted; they will call EMS personnel to resolve the problem. Medical Center Police may notify the AO/R or the ACOS/R to advise them of the problem.

6.3.8 Disaster Planning
6.3.8.1 Fire
In the event of a fire, the RACE procedure should be implemented:
- (R)emove yourself and others from danger.
- (A)ctivate an alarm pull box or call extension 2222.
- (C)onfine the fire by closing doors.
- (E)vacuate personnel from the area.

Employees are instructed to evacuate their work area/building until VA Police Service or the Cleveland Fire Department issues further instructions.

Research Investigators will be notified regarding the status of their animals as soon as possible. Any alterations in the routine care of the animals will be addressed at this time. In the event that a fire has occurred after hours, an attempt will be made to notify all ARF employees to report to work. The Consulting Veterinarian, ACOS and A/O will also be notified by Police Services to assess the situation.

Animals will be checked as soon as access to the facility is permitted by fire and police personnel. Animals suffering from injuries or smoke inhalation will be examined and treated as quickly as possible. Seriously injured animals will be euthanized as deemed necessary by the Consulting Veterinarian. Dead animals will be removed from cages and placed in the ARF cold room. An alternate cold room may be utilized if the ARF cold room has been damaged.

If a fire has destroyed the proper housing of animals, they will be relocated to alternate rooms. In the event that any of the animal feed supply is destroyed, the local feed vendor will be contacted for immediate replacements. Any feed that cannot be obtained from the local vendor will be ordered for overnight delivery from the distributor. Spoiled or
contaminated feed will be discarded. If the water supply is affected, water will be brought in from another facility.

Electrical power and the ventilation system are the responsibility of Engineering Service. If electrical power is lost for an extended period of time, the emergency generators will be activated. Contamination control will be handled by ARF personnel and EMS. This will entail the cleaning up of any smoke and/or water damage. If the air handling system is functional, all air filters in the affected areas will be changed.

Animal rooms designated “Quarantine” will not be moved due to the possibility of contaminating other animals or personnel. The ARF Supervisor, the Consulting Veterinarian, the ACOS and A/O will decide whether the animals will be relocated. Human life is not to be jeopardized.

6.3.8.2 Flooding
If flooding is anticipated, animals will be relocated. Animal rooms designated “Quarantine” will not be moved due to the possibility of contaminating other animals or personnel. If relocation is not possible, animals will be moved to the highest row within their racks and monitored frequently. Research Investigators will be notified regarding the status of their animals as soon as possible. Any alterations in the routine care of the animals will be addressed at this time. In the event that a flood has occurred after hours, an attempt will be made to notify all ARF employees to report to work. The Consulting Veterinarian, ACOS and A/O will also be notified by Police Services to assess the situation.

In the event of a water main break, where severe flooding occurs, personnel are not permitted to enter an animal room until engineering personnel have granted clearance. Animals suffering from injuries or exposure will be examined and treated as quickly as possible. Seriously injured animals will be euthanized as deemed necessary by the Consulting Veterinarian. Dead animals will be removed from cages and placed in the ARF cold room. An alternate cold room may be utilized if the ARF cold room has been damaged.

Sandbags will be provided by Engineering Service to aid in keeping water from entering non-affected animal rooms. If a flood within the facility damages the feed supply, the local vendor will be contacted for immediate delivery of new feed. Spoiled or water damaged feed will be discarded. The City of Cleveland will test the quality of the water if widespread flooding occurs. Bottled water may need to be brought in until the City of Cleveland has proven that the water supply is safe for consumption. Floors, equipment, etc. will be cleaned and disinfected immediately by ARF personnel and EMS. This will aid in the prevention of possible contamination.

6.3.8.3. Tornado
In the event of a tornado, all personnel will be informed of an impending storm via overhead announcement. In outlying areas, employees must move into center corridors against walls and away from doorways and windows. Animals are not to be moved in the event of a tornado. Human life is not to be jeopardized.

Animals will be checked as soon as access to the facility is permitted by fire and police personnel. Animals suffering from injuries will be examined and treated as quickly as possible. Seriously injured animals will be euthanized as deemed necessary by the
Consulting Veterinarian. Dead animals will be removed from cages and placed in the ARF cold room. An alternate cold room may be utilized if the ARF cold room has been damaged.

In the event that a tornado has occurred after hours, an attempt will be made to notify all ARF employees to report to work. The Consulting Veterinarian, ACOS and A/O will also be notified by Police Services to assess the situation. Research Investigators will be notified regarding the status of their animals as soon as possible. Any alterations in the routine care of the animals will be addressed at this time.

If any or all feed is damaged or destroyed due to a tornado, the local vendor will be contacted for replacements. If needed, feed will be shipped by overnight delivery. Spoiled or contaminated feed will be discarded. If a tornado has disrupted the water supply to the ARF, water will be transported in from other facilities. If a tornado has destroyed the proper housing of animals, they will be relocated to alternate rooms.

The HVAC Shop will be contacted immediately to assess the air handling system. Large fans and cooling units will be used until the necessary repairs have been made. Depending on the estimated time for repair, animals may be relocated to a more suitable area. Animals that cannot be readily relocated (e.g. in testing chambers) will be monitored frequently.

6.3.8.4. Bomb Threat/Bombing
If a bomb threat is received, the call shall be immediately reported to the VA Police and Security Office at extension 2222. All employees must evacuate the facility if:
- A bomb threat has been received.
- A bombing occurs.

Employees are instructed to evacuate the area/building until the VA Police and Security Office issue further instructions. Human life is not to be jeopardized. Research Investigators will be notified regarding the status of their animals as soon as possible. Any alterations in the routine care of the animals will be addressed at this time.

In the event that a bombing has occurred after hours, an attempt will be made to notify all ARF employees to report to work. The Consulting Veterinarian, ACOS and A/O will also be notified by Police Services to assess the situation.

Animals will be checked as soon as access to the facility is permitted by fire and police personnel. Animals suffering from injuries or smoke inhalation will be examined and treated as quickly as possible. Seriously injured animals will be euthanized as deemed necessary by the Consulting Veterinarian. Dead animals will be removed from cages and placed in the ARF cold room. An alternate cold room may be utilized if the ARF cold room has been damaged.

If a bomb or subsequent fire has destroyed the proper housing of animals, they will be relocated to alternate rooms. In the event that a portion or all of the animal feed supply is destroyed, the local feed vendor will be contacted for immediate replacements. Any feed that cannot be obtained from the local vendor will be ordered for overnight delivery from the distributor. Spoiled or contaminated feed will be discarded. If the water supply is affected, water will be brought in from another facility.
Electrical power and the ventilation system are the responsibility of Engineering Service. If electrical power is lost for an extended period of time, the emergency generators will be activated.

Contamination control will be handled by the cleaning up of any bomb residue, smoke, and/or water damage by ARF personnel and EMS. If the air handling system is functional, the HVAC Shop in Engineering Services will change all air filters in the affected areas.

6.3.8.5 Protests by Animal Rights Activists/Threats of Terrorism
If a scheduled protest, an unscheduled protest, or an animal rights activist threat is received, the VA Police Service is to be contacted immediately at extension 4207. VA Police Service will determine what action should be taken in such an event. Personnel in the ARF are not to approach anyone who may cause harm to the animals, personnel, or the facility.

6.3.8.6 Break In
Any break in will be reported to VA police at extension 4207.

Animals that may be loose in the ARF due to vandalism will be captured, identified, and returned to cages. The Consulting Veterinarian will assess the condition of the animals, and may euthanize them if necessary. Any animals that die as a result of vandalism will be disposed of in the ARF cold room. If the cold room has also been damaged, an alternate cold room will be utilized until it has been repaired. In the event that a break-in has occurred after hours, an attempt will be made to notify all ARF employees to report to work. The Consulting Veterinarian, ACOS and A/O will also be notified by Police Services to assess the situation.

If the feed has been destroyed and/or tampered with, it will be immediately discarded. An order for the replacement of feed will be placed with a local vendor or shipped in by overnight delivery if needed. In the event that the water supply has been disrupted, fresh water will be brought in from another facility until repairs have been made. The HVAC Shop (Engineering Service) is responsible for the ventilation and heating/cooling systems. If vandalism to this system has occurred, they shall be contacted immediately.

6.3.9 Species Specific Husbandry Procedures
Before starting in each room, check the treatment list on individual cage cards or on the board for any specific instructions. As each room is completed, the activity in the room, e.g., cages changed, feed and water provided and temperature, should be initialed on the room log. Housing that occurs outside the ARF (in the lab) should follow the same husbandry practices and timelines outlined for the specific species housed. Laboratory staff will assume all husbandry responsibilities when housing in the lab space.

6.3.9.1 Cat Husbandry Procedures
6.3.9.1.1 Housing and Enrichment
Cats are group housed and are provided with at least 1 perch to lie on. The perches are of varying shapes, sizes, heights and materials to increase stimuli and to accommodate the varying tastes of the cats. Beds are in the form of crates, boxes and pillows. The cats are provided with numerous scratching posts of varying materials. All hard surfaces are covered with drapes to aid in the enjoyment of the cats and to collect hair as they lie on
them. The technical staff plays with the cats each day and gives each cat individual attention.

6.3.9.1.2 Daily Husbandry
Replace empty water bowls with clean bowls and fill with water. Fill all food bowls. Ensure that all animals are eating, drinking, urinating and defecating. Any animal noted with abnormal findings should be identified and the ARF supervisor, veterinarian and PI notified.

Check cages for sick or dead animals. Bag and identify any dead animals and place in the cold room for postmortem examination. Report all sick or dead animals to the ARF Supervisor, veterinarian and PI. Check the room temperature and humidity and records on the room’s log. The temperature should be about 20-22°C (68-72°F).

Scoop out all the clumped litter and fill litter pans if necessary. Weigh cats before the AM feeding at a frequency specified in the protocol or as recommended by the Consulting Veterinarian and record in kg. Cats are fed ad libitum. Clean the sink, counter and door and wipe dry. Refill the paper towels and soap dispensers, empty the wastebasket and sweep and mop the floor. Record any treatments done to animals on their record and initial. Lock the door when finished.

6.3.9.1.3 Semi-Weekly Husbandry
Empty litter pans and replace with clean litter pans and litter. Replace cloth bedding in crates and on perches. Send dirty bedding to laundry.

6.3.9.1.4 Weekly Husbandry
Check the room air filter and change if necessary. Vacuum all loose hair in the room and around and within the vents. Scrub the floor.

6.3.9.1.5 Monthly Husbandry
Change the food and litter hoppers and cage wash. Place cats in cages and remove from room or move cats to another room. Remove everything from the room and sweep the floor. Using a hose with a power head, spray down the walls, vents, ceiling and door with hot water. Cover the thermostat to protect it from water. (A latex glove works well). Squeegee the floor and allow room to dry. Run all crates, shelves scratching posts and toys through the cage washer. Trim nails if necessary.

6.3.9.1.6 Quarterly Husbandry
Scrub the floor with the scrubber or schedule with EMS.

6.3.9.2 Dog Husbandry Procedures

6.3.9.2.1 Housing and Enrichment
Dogs are housed in separate cages or runs in D-34. Dogs are let out of their runs each day to play within D-34 with the other dogs. If applicable, dogs are exercised outside 3 times per week. Dogs are given Bio-serve beef treats in their toys each day. Each dog is given a variety of toys to play with and chew on in their runs. Those toys include: ball, gumabone, kong, Hercules dental kong, and spaceship treat holders. The technical staff plays with the dogs each day and gives each dog individual attention.

6.3.9.2.2 Daily Husbandry
Replace empty water bowls with a clean water bowl filled with fresh water. Make sure all dogs on automatic watering have a fully functional water valve. Work from pen to pen to ensure that no cages are missed. Feed each dog two times daily, at 8:30 AM and 3:00 PM, following any special instructions posted on the animals’ run. Pay close attention to special diet instructions and amount of feed to be given.

Ensure that all animals are eating, drinking, urinating and defecating. Any animal noted with abnormal findings should be identified and the ARF supervisor, veterinarian and PI notified. Check cages for sick or dead animals. Bag and identify any dead animals and place in the cold room for postmortem examination. Report all sick or dead animals to the ARF Supervisor, veterinarian and PI. Check the room temperature and humidity and records on the room’s log. The temperature should be about 20-22°C (68-72°F).

If the animals are in the runs, remove the animal from the run, thoroughly hose down the run using the high pressure sprayer and return the animals to the run when clean.

Spray down the walls and squeegee the floor. Clean debris from all the floor drains. Clean the sink, counters and door and wipe dry. Refill paper towels and soap dispensers. Empty the wastebasket. Sweep and mop the floor. Lock the door when finished.

6.3.9.2.3 Weekly Husbandry
Check the room air filter and change if necessary. Vacuum all loose hair in the room and around and within the vents. Scrub the floor.

6.3.9.2.4 Monthly Husbandry
Remove everything from the room and sweep. Using a hose with a power head, spray down the walls, vents, ceiling and doors using hot water. Cover the thermostat to protect it from water (a latex glove works well). Change the automatic water filters and flush the automatic lines with plain water. Return everything to the room.

6.3.9.2.5 Quarterly Husbandry
Weigh the dogs, trim the dogs’ nails and brush out the animals (more frequently if needed). Scrub the floor with the scrubber or schedule with EMS.

6.3.9.2.6 Semi-Annual Husbandry
Flush the automatic water lines with bleach followed by a 20 minute rinse with plain water or until no bleach remains in the line.

6.3.9.3 Rabbit Husbandry Procedures

6.3.9.3.1 Housing and Enrichment
Rabbits are given toys in their cages at all times. Each rabbit has a stainless steel rattle hanging from the top of the cage and a dumbbell to push around in their cage. Rabbits are given 2 alfalfa cubes in the morning and 2 in the afternoon to chew on. Rabbits are given 1 bunny block on a chain twice a week. Animal facility staff pets, grooms and socializes each rabbit on a daily basis.

6.3.9.3.2 Daily Husbandry
Replace empty water bottles with fresh water. Check feed levels. Feed each rabbit ½ cup in the AM. Check feeders for cleanliness and clean and replace if soiled. Work from rack to rack to ensure that no cages are missed.

Ensure that all animals are eating, drinking, urinating and defecating. Any animal noted with abnormal findings should be identified and the ARF supervisor, veterinarian and PI notified. Check cages for sick or dead animals. Bag and identify any dead animals and place in the cold room for postmortem examination. Report all sick or dead animals to the ARF Supervisor, veterinarian and PI. Check the room temperature and humidity and records on the room’s log. The temperature should be about 20-22°C (61-72°F).

Remove each cage pan, discard the excreta in the dump station, rinse the pan with water, rinse with acid to remove urine scale, rinse again with water and replace. Repeat procedure for each cage pan. Clean the sink, counter, and door and wipe dry. Refill the paper towel and soap dispensers. Empty the wastebaskets. Sweep and mop the floor. Lock the door when finished.

6.3.9.3.3 Weekly Husbandry
Collect all bottles and feeders from the room and put them through the bottle washer. Retrieve clean cages from the storage area. Starting with the top left cage, 1st remove the cage card and place it on the new cage, then open the cage door. Grasp the rabbit with 1 hand by the loose skin of the neck and pull it out of the cage. Then supporting the weight of the rabbit with the other hand, move it to the new cage. Close the door and move on to the next rabbit. Rabbits are housed together by project or study. Do not change their positions in racks unless requested.

Remove all dirty pans and cages to the cage wash area for cleaning. Remove the floor grates and scrape any fecal material into the flush drain and then return the floor grates to the cage. After all the grates are scraped, push the racks into the cage washer. Cages are to be washed by hand to remove the urine scale. Trays should be dumped and scraped into the floor flush drain, then stacked. Protective gloves, glasses and clothing must be worn during the next procedure. Wearing goggles, nitrile gloves and a plastic apron, pour approximately 1.5 cups acid descaler (a phosphoric acid based scale and milk stone remover) into the 1st pan. Using a scrub brush or pad, scrub out the pan, then dump acid into the next pan (good for about 9 pans before taking new acid) and rinse the 1st pan well in the sink. Immediately report any accidents (acid spills) to the ARF supervisor. When completed, return all trays to the rack and push the cages into the cage washer and run the cycle.

Vacuum all the loose hair in the room and around and within the vents. Mop the area behind the racks, and then push the racks back against the wall and mop out the rest of the room. Return water bottles to the cages. Clean off the sink, counter and door. Empty wastebaskets and refill paper towel and soap dispensers. Check the room air filter and change if needed.

6.3.9.3.4 Monthly Husbandry
Remove everything from the room and sweep. Using a hose with a power head, spray down the walls, vents, ceiling and doors using hot water. Cover the thermostat to protect it
from water (a latex glove works well). Squeegee the floor and let dry. Return everything to the room.

6.3.9.3.5 Quarterly Husbandry
Weigh the rabbits, trim nails and brush the animals (more frequently if needed)

6.3.9.3.6 Nails and teeth
The technique described is for 1 person working alone. An additional person is often useful in restraining the rabbit during the procedures.

Grasp the rabbit with 1 hand by the loose skin of the neck and support it with the other hand. Place the rabbit on a cloth drape or blanket. Pull the cloth over the rabbit’s head (this will keep it still while you clip the nails). Gently pull 1 leg at a time from under the drape and cut the nails just above the quick. When all nails have been cut, remove the drape from the rabbit’s head.

Gently insert the eraser end of a pencil in the side of the rabbit’s mouth (this will cause him to chew on it, exposing his teeth). If the bottom teeth are overgrown, they will protrude right between the lips and are very obvious. If the top teeth are overgrown, they will generally curve down and toward the back of the mouth. They are less obvious and need to be carefully checked. If the teeth need to be cut, turn the rabbit on its back and rest his body on your lap. When the animal is calm, cut the teeth with the nipper to obtain the proper tooth alignment. Return the rabbit to the cage. Rabbit teeth should be trimmed only under the direction of a veterinarian.

Fill out each animal’s record for treatments given and initial.

6.3.9.4 Rodent Microisolator Husbandry Procedures
6.3.9.4.1 Housing and Enrichment
Rodents are housed socially in microisolator shoebox cages unless different housing has been approved in the IACUC ACORP. Proper microisolator technique is essential to prevent disease transmission between animals. Rats are provided with tunnels and nylabones in their cage as enrichment. Mice are provided with huts, tunnels, nestlets and guma bones as enrichment. All singly housed rodents will receive enrichment unless specifically noted “no enrichment” on the cage card after approval by the IACUC as scientifically justifiable.

6.3.9.4.2 Daily Husbandry
A lab coat or gown is required for entry into microisolator rooms. A fresh surgical gown, cap mask and gloves must be worn whenever cages are opened. Cages must only be opened within an operating laminar flow work bench. The hood must be turned on a minimum of 5 minutes before use.

When checking cages for food and water, move around the room in an orderly fashion, rack to rack to avoid missing any cages. Check for any flooded or heavily soiled cages. Ensure that all animals are eating, drinking, urinating and defecating. Any animal noted with abnormal findings should be identified and the ARF supervisor, veterinarian and PI notified. Check cages for sick or dead animals. Bag and identify any dead animals and place in the cold room for postmortem examination. Report all sick or dead animals to the ARF.
Supervisor, veterinarian and PI. In breeding colonies, check for newborn litters and record them on their cage cards.

Spray all surfaces of the hood except the air supply plenum with Clidox. Wipe all surfaces with a Clidox soaked paper towel or clean cloth. Lay several layers of paper towel or a clean cloth on the surface of the hood. Soak the towels with Clidox. Re-spray towels periodically to prevent drying. Take a sterile cage or stack of cages from the rack; place the cage/stack in the hood. Place a container of sterile water filled bottles inside the hood and wipe down with Clidox.

Remove the microisolator lid and place open side down on the wet towel. Spray or wet all surfaces of your gloves with Clidox prior to entering the cage. Gloves must be wet for Clidox to be effective. Similarly, wipe the sides of the cage (wipe sides, top, and bottom of shipping cartons) already holding the mice and place this inside the hood. NOTE: When wiping the cage with Clidox be sure not to get the filter wet as this will ruin the integrity of the filter. Open this crate or cage. If a tool is required for opening the carton, it should be wiped with a towel dampened the Clidox solution. If using forceps to transfer animals, wipe with a towel dampened with Clidox, and use to transfer the mice by their tails. Tip-protected forceps should be dip in Clidox between cages or dip your hand in Clidox and use your fingers/hand to transfer the animals into a clean cage.

Take a sterilized water bottle, spraying or wiping its surface with Clidox. Attach the cage card and replace the microisolator lid. Transfer the microisolator unit to the housing rack in the room and repeat this procedure for each cage change/new rodent entering the facility. When finished changing/transfering spray the work surface with the Clidox solution. Rinse off the forceps with water and dry with a clean paper towel.

In the event that a mix-up of animals occurs, it is imperative that it be reported to the principal investigator immediately. To prevent this from happening only one cage at a time should be within the laminar flow hood. In the event that there are "escapee" animals, place the animal or animals in a separate cage with a cage card noting when, where, who found them and call the principal investigator as soon as possible.

Wipe down the outside (sides and top) of the hood with and wipe dry with clean paper towels. Remove and discard the paper or cloth liner on the hood surface. Turn off the hood. Sweep and mop the floor. Empty wastebaskets, fill the paper towel and soap dispensers. Check the room temperature and humidity and records on the room’s log. The temperature should be about 20-22°C (61-72°F). Lock the door when finished.

6.3.9.4.3 Weekly Husbandry
Check the room air filter and change if necessary. Vacuum all loose bedding in the room and around and within the vents. Scrub the floor.

6.3.9.4.4 Monthly Husbandry
Remove everything from the room and sweep the floor. Using a hose with a power head, spray down the walls, vents, ceiling and door with hot water. Cover the thermostat to protect it from water. (A latex glove works well). Squeegee the floor and allow room to dry. Replace everything in the room.
6.4 Population Management

6.4.1 Identification
All animals housed within the ARF have adequate means of identification. Means of animal identification include room, rack, pen, and cage cards with written or bar-coded information; colored stains; ear notches and tags; tattoos; subcutaneous transponders; and freeze brands. Toe-clipping, as a method of identification of small rodents, is used only when no other individual identification method is feasible and is performed only on altricial neonates.

Identification cards should include the following information:
- Investigator name and phone extension
- Animal species and strain
- Number and sex of animals in the cage
- Date the animal was received
- Animal date of birth
- Protocol number

6.4.2 Records
Clinical records for individual animals should be maintained for all animals. Basic demographic information and clinical histories should be readily accessible to investigators, veterinary staff, and animal-care staff. They should include:
- Pertinent clinical and diagnostic information
- Date of inoculations
- History of surgical procedures and postoperative care
- Information on experimental use
- Surgical and Post-Surgical Records

Medical records for USDA-covered species are maintained in in the ARF in 8” x 11” sheets in binders. Medical records for rodents are maintained on the cage card, blue surgery card, purple procedures card or pink medical card.

6.4.3 Documentation of Animal Numbers
As required by the Animal Welfare Act and PHS Policy, the number of live animals utilized for research purposes in the ARF is tracked. A monthly census of adult animals is maintained and tracked per investigator. Animals bred in-house are tracked as adults from weaning. The addition of the number of sacrificed pups to the number of adult animals represents the total number of animals utilized under any protocol. Animals used in VA sponsored research must be recorded on the Continuing Annual Review yearly. Animals housed at the VA are recorded for the VA whereas animals housed off site (affiliate) are reported by the affiliate. This is to prevent double counting of animals utilized for research.

6.4.4 Genetics and Nomenclature
Genetic monitoring and nomenclature is performed to ensure the accuracy of species and strain designations in the animal colony. During protocol preparation the investigator must review the current literature and be aware of what strains and substrains of animals are necessary to successfully complete their research program. During the pre-review process, the consulting veterinarians are available for consultation on species, strain and stock choice.
6.4.5 Adoption of Research Animals
When a principal investigator determines that an animal is no longer useful for research purposes, they may request that the animal(s) be offered for adoption as a suitable alternative to euthanasia. The consulting veterinarian and ARF supervisor will evaluate individual requests for adoption of research animals owned by and housed at the VA. The attending veterinarian from CWRU Animal Resource Center may be contacted in the absence of the VA consulting veterinarian and/or if the animal to be adopted is part of a CWRU protocol. The IACUC does not need to be involved for routine adoptions; however, members will be informed of any adoption placement.

Only those individuals who are knowledgeable about the routine care of such animals and who can assure that the animal will be maintained as a pet, may adopt a research animal.

6.4.5.1 Restrictions on Animals Placed for Adoption
Only animals that are healthy and have not been rendered permanently incapacitated, debilitated, or disfigured may be released for adoption. Animals that have been infected with agents that are hazardous to humans, or treated with any radioactive, biohazardous, carcinogenic or toxic substances that pose a risk to humans, may NOT be released for adoption. Only animals for which ownership is not prohibited or restricted by local, state or federal law (other than routine dog registration) may be released for adoption.

6.4.5.2 Requirements for Approval of Adoption
The ARF supervisor, consulting veterinarian and/or the CWRU veterinarian will determine the suitability of the animal for adoption and adhere to this policy. The Principal Investigator must provide a statement certifying that:
- The animal is no longer needed for the research protocol
- The animal has not been infected with agents hazardous to human or treated with any radioactive, biohazardous, carcinogenic or toxic substances that pose a risk to humans

The applicant agrees to absolve the VA and its officers, employees and agents of all liability associated with, and responsibility for, said animal. The applicant agrees not to transfer ownership of this animal and agrees to abstain from any monetary gain associated with the animal. The applicant may not authorize euthanasia for nonmedical reasons, without written consent of the veterinary consult at the VA. The Authorization to Adopt an Animal Owned by the VA or CWRU form must be completed prior to the release of any animal for adoption. This form is located in Appendix 11.

6.4.6 Breeding
A breeding colony may be necessary to develop an animal model that is not commercially available, or to produce young animals of a specific age or weight that cannot be provided by a commercial breeding colony. Investigators developing a new spontaneous or induced mutant animal model might also need to maintain their own breeding colony because there is no alternative source for the animal model. In addition, if the species/strain is commercially available, the production of these animals should be carefully justified on scientific grounds. Cost savings alone is NOT a valid justification.

6.4.6.1 Pain and Suffering Concerns for Genetically Modified Strains
Any debility that genetically modified animals may experience is a cause of concern. It is important to provide as much support and comfort for mutant animals as possible. Some
strains may require specific husbandry interventions to enable or promote well-being. The general health of novel genetically modified animals should be assessed soon after their availability. In case a severe debilitating phenotype develops, the PI must provide the IACUC with this information in writing when the new mutant has been developed or at the next annual review of the animal-use protocol. Examples of severe phenotypes include abnormal behavior (circling, flipping), adverse anatomical changes (malocclusion, missing limb), adverse physiologic or organ dysfunction (progeria, lacking essential liver enzymes), etc. that impacts on the animals’ health and well being. If health concerns are identified, please describe how the animals will be assessed and managed. Next, identify humane endpoints for removal from the study.

6.4.6.2 Breeding Records
For proper and efficient colony management, it is essential that breeding records be maintained. These records should be available for review during regular business hours.

Minimal record keeping should include:
- The species and strain designation (e.g., C57BL/6J, B6D2F1, etc.)
- All phenotypes and genotypes
- Breeder identification numbers (each breeding animal should have a unique identifier that is not repeated in subsequent generations)
- Set-up date (mating date)
- Breeder date of birth (DOB)
- An accounting of all colony offspring including:
  o Animals weaned and retained for colony maintenance
  o Animals used for research
  o Culled littermates (e.g., undesired genotype)

6.4.6.3 Weaning and Separating Rodents
6.4.6.3.1 Detecting Pregnancy
Pregnancy can be determined by weighing the female(s), visual inspection and by palpation. Record the delivery date on the breeding pair’s cage card. Record the numbers of pups born in each litter and how many litters the adult female has delivered.

6.4.6.3.2 Counting days from birth
The day of parturition is day zero (0). The counting of days begins the day following birth, e.g., Tuesday is day one (1) if pups are born on Monday.

6.4.6.3.3 Pair Mating
One male may be left with one female and one litter of pups, provided the pups are weaned between 3-4 weeks of age or until the birth of the next litter, whichever is sooner.

6.4.6.3.4 Harem Mating
One male may be placed with a breeding group of up to two females and 2 litters of pups until 7 days (1 week) of age, at which time one mother and half of the pups must be removed and placed in a new cage. New cages must be marked and linked to the source cage.

6.4.6.3.5 Weaning
Based on the breeding scheme used, the PI or lab member must wean litters by either 3-4 weeks of age.
- Exemptions are allowed if outlined in an IACUC-approved protocol.
- PI or lab member must separate and house pups at a cage density of no greater than four adult males or five adult females per cage.
- PI or lab member is responsible for weaning and sex-separating the pups by the IACUC approved protocol deadline
- PI or lab member must record complete information (PI name, protocol number, species, strain, source: in-house bred, date of weaning, and gender) on new cage cards when weaning pups.

6.4.6.3.6 Noncompliance
Cages identified as having more than twice the maximum number of rodents (severely overcrowded cages) must be separated by the end of the work day on which they are reported. The investigative team will have 2 days to separate moderately overcrowded cages. If the investigative team fails to separate the cages within these timeframes, ARF personnel will do the separation and the PI’s program may be charged a fee for this service.

6.5 Animal Facility Photography
Photography within the laboratory and animal facilities must have prior approval for photography from the ARF Supervisor, A/O or ACOS and the consulting veterinarian and must be in accordance with the following stipulations:
- Appropriate personal protective equipment must be worn by all persons in the photograph keeping species of animal and procedure demonstrated in mind.
- Appropriate handling and restraint methods for the species must be used.
- All procedures shown must be described in the approved ACORP for that particular animal.
- All attempts should be made to have animals in clean surroundings, cleans cages or clean pens with clean accessories. Water bottles and feeders should be full if visible in the photo.
- The Principal Investigator must give approval for photographs to be taken of their animals.
- No references to personal information should be visible in the photo (this includes PI name, cage cards, ACORP info etc).
- All photos must be stored on VA approved equipment in accordance with research data storage procedures.

6.6 Transportation, Relocation or Reassignment of Animals
All transportation of animals, including intra-institutional transportation, occurs only when essential since any transit time introduces risks of exposure to environmental extremes, crowding, infectious agents, and possible zoonoses, which can affect animal and public welfare, and the consistency of results.

Transporting of animals to research laboratories, procedural, or testing areas outside of an animal facility may jeopardize the integrity of research data, impairs regulatory oversight, and abrogates the implementation of uniform standards of animal care and use within those areas, and requires strong written scientific or logistical justification. Movement of animals within animal housing rooms is discouraged. Movement of animals between animal housing rooms of a single facility may only occur with the consent of the ARF Supervisor.
If any vertebrate animals are transported outside of ARF facility but within a building, the service elevator must be used. All cages and other containment devices used to transport vertebrate animals outside of the ARF but within a building must be covered with an opaque material to contain allergens and to prevent public viewing. Empty cages must be covered with an opaque material when outside of ARF facilities. Soiled cages contain allergens.

When transporting animals between buildings, the following additional requirements apply:
- In extremes of temperature (<50°F and >85°F), extra measures must be taken to protect animals from the elements, to ensure rapid transport between buildings.
- Cage lids must be secured to the cages with a clip, tie, or residue-free tape to prevent escape of the animal.
- Single occupied cages may be carried by hand. If more than one cage is transported, these must be transported on or in a cart. The cages must be secured to the cart in a manner such that if the cart were to tip over, the cages would stay and not be thrown from the cart and would not open. Suggestions include a bungee-type cord or a cart with an inner area to securely transport the cage.

Transfer of unused animals from one IACUC-approved use to another IACUC approved one is permitted only when requested in writing and approved by the ARF Supervisor.

Shipment of animals to/from other institutions must be requested in writing to the ARF Supervisor or his/her designee. When animals are transferred out of the ARF an initial request will be made by the PI to the ARF Supervisor or his/her designee. The ARF Supervisor will coordinate with the veterinarian or his/her designee, who will then be in contact with the receiving institution’s representative. The receiving institution will be sent, upon request, current health and serology reports for approval. Once approval has been received, the ARF Supervisor then coordinates with the receiving institution the date and means of shipment. On the day of shipping, investigative staff, in conjunction with ARF staff, will pack the animals. Prior to shipment, the ARF Supervisor will visually check the health status of the animals and a current health report of the animals will be included with shipment.

When animals are transferred into the ARF an initial request will be made by PI to the ARF Supervisor or his/her designee. The ARF Supervisor or his/her designee will contact the representative of the sending institution requesting current health and serology reports be sent for review and approval by the ARF Veterinarian or his/her designee. Once approval is received, the ARF Supervisor or his/her designee will then coordinate the shipping/receiving date and means of transportation with the sending institution.
7 Veterinary Medical Care

7.1 Animal Procurement and Transportation

All animals are acquired lawfully, and the Cleveland VAMC makes reasonable attempts to ensure that all transactions involving animal procurement are conducted in a lawful manner.

Potential vendors are evaluated by the veterinarians for the health status and quality of animals supplied by them. Vendors regularly provide information that describes the genetic and pathogen status of their colonies or individual animals. This information is used for deciding on acceptance or rejection a particular vendor as an “approved” vendor and similar data is obtained on animals received by transfer. No USDA Class B dealers are used by the LSCDVAMC.

Once an ACORP has received IACUC and R&D approval, an animal order tally sheet is completed by the IACUC Coordinator and given to the ARF technicians for inclusion in the Animal Ordering Book. The Investigator who wishes to order animals will complete their ordering form as appropriate to their funding source and submit the order to an ARF technician who will then verify the animal species, strain, gender and number from the animal order tally sheet. The technician will subtract the number of animals being ordered, sign the order form as approved and give to the Research Purchasing Clerk. The clerk will then order the animals as described and they will arrive per the preapproved shipping schedule with the warehouse.

Each shipment of animals is inspected for compliance with procurement specifications and signs of clinical disease. Animals from “approved” vendors may be housed directly in a vendor-specific room. All non rodents require 7 days of acclimatization prior to survival experimental use. A seven day acclimatization period for rodents is recommended but not required.

Coordination of ordering and receiving with the ARF supervisor and technicians are done to ensure that animals are received properly and that appropriate facilities are available for housing. Shipments of animals from other institutions must be approved by the ARF Supervisor.

All transportation of animals, including inter-institutional transportation, is planned to minimize transit time and the risk of zoonoses, reduce exposure to rodent allergens, protect against environmental extremes, avoid overcrowding, provide food and water when indicated, and protect against physical trauma. Some transportation-related stress is inevitable, but it is minimized by attention to those factors.

The ARF staff maintains the paperwork on the shipments and transfers. Animals from non standard sources are delivered by commercial services specializing in animal transport. Transport of animals between the LSCDVAMC and CWRU and the LSCDVAMC and the Cleveland Clinic (CC) are provided by CWRU Animal Resource Center vehicles and CC Biological Resources Unit vehicles, respectively.

7.1.1 Purchasing Animal Organs, Tissues or Antibodies from Outside Vendors

The purchase of standardized, commercially available reagents or custom-made antibodies produced from animals does not normally require IACUC notification or approval. Although
IACUC approval may not be indicated, IACUC notification is essential to determine whether potential zoonoses are animal pathogens are present and to verify, in the case of custom-made antibodies that vendors have an assurance on file with OLAW as required.

The same is true for tissues and organs procured from organ banks and slaughterhouses. However, if the reagents are to be used in animals, documentation must be available to demonstrate that the reagents free of any animal pathogens. This documentation may include mouse antibody production (MAP), rat antibody production (RAP) test results or PCR analysis for specific animal pathogens.

7.2 Preventive Medicine
Disease prevention is an essential component of comprehensive veterinary medical care program. Effective preventive-medicine programs enhance the research value of animals by maintaining healthy animals and minimizing non-protocol sources of variation associated with disease and unapparent infection. Our program consists of various combinations of policies, procedures, and practices related to quarantine and stabilization and the separation of animals by species, source, and health status.

Upon arrival, the ARF supervisor checks all animals and reviews their health records. The Consulting veterinarian performs a physical examination of all USDA covered species on his or her next visit (within 2 or 3 days).

Dogs receive booster vaccinations of Quantum 6 (canine distemper, adenovirus type 2, parainfluenza, parvovirus, and leptospira bacterin) at yearly intervals. Dogs are not vaccinated for rabies. Dogs receive a physical exam including weight and nail trim at least quarterly. Dental cleaning is provided when indicated. Random intermittent or direct fecal examination of dogs with clinical signs of endoparasitism is done.

Cats are vaccinated yearly with Fel-O-Guard Plus 4+Lv_K (MLV) (panleukopenia / rhinotracheitis / calici / chlamidia / FeLV). Cats receive a physical exam including weight and nail trim at least quarterly. Dental cleaning is provided when indicated. Random intermittent or direct fecal examination of cats with clinical signs of endoparasitism is done.

Rodents are monitored through the sentinel animal profile on a quarterly basis. CWRU ARC provides this service. The CWRU ARC monitors the health status of rodents in all housing areas including satellite facilities and monitors the LSCDVAMC quarterly with serology and pinworm testing, and yearly with complete parasitology and bacteriology tests and gross pathology observations.

7.2.1 Quarantine, Stabilization and Separation
Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined.

An effective quarantine minimizes the chance for introduction of pathogens into an established colony. The animal research facility has procedures for evaluating the health and the pathogen status of newly received animals, and the procedures reflect acceptable veterinary medical practice and federal and state regulations applicable to zoonoses.
Information from vendors on animal quality is sufficient to enable the Veterinarian, ARF Supervisor and/or ARF technicians:
- To determine the length of quarantine,
- To define the potential risks to personnel and animals within the colony,
- To determine whether therapy is required before animals are released from quarantine, and, in the case of rodents, to determine whether cesarean rederivation or embryo transfer is required to free the animals of specific pathogens.

Rodents do not require quarantine if received directly from approved vendors. The CWRU Veterinary Services provides oversight of animals from nonstandard sources that will be housed at the LSCLVAMC. Rodents from nonstandard sources with an acceptable health status are housed in microisolator caging on a “change last” status and treated prophylactically for endo- and ectoparasites until confirmatory retesting or experimental euthanasia. Rodents possessing unwanted pathogens are quarantined at CWRU and re-derived by embryo transfer or hysterectomy before transfer to the LSCLVAMC.

When quarantine is indicated, animals from one shipment are separated from animals from other shipments (not necessarily from each other) to preclude transfer of infectious agents between groups. Regardless of the duration of quarantine, newly received animals are given a period for physiologic, psychological, and nutritional stabilization before their use. The length of time for stabilization depends on the type and duration of animal transportation, the species involved, and the intended use of the animals.

Physical separation of animals by species is required to prevent interspecies disease transmission and to eliminate anxiety and possible physiologic and behavioral changes due to interspecies conflict. Such separation is accomplished by housing different species in separate rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators are used if rooms are not available. In some instances, it might be acceptable to house different species in the same room, for example, if two species have a similar pathogen status and are behaviorally compatible.

### 7.2.2 Surveillance, Diagnosis, Treatment, and Control of Disease

Standard methods of disease surveillance, disease prevention, diagnosis, and therapy utilizing currently accepted veterinary practice are performed.

All animals are observed for signs of illness, injury, or abnormal behavior by the ARF staff daily. More-frequent observations are done when warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. Professional judgment is used to ensure that the frequency and character of observation minimize risks to individual animals.

Unexpected deaths and signs of illness, distress, or other deviations from normal in animals are reported promptly to the veterinarian(s), investigator and ARF Supervisor to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease are isolated from healthy animals in the colony. If an entire room of animals is known or believed to have been exposed to an infectious agent, the group is kept intact during the process of diagnosis, treatment, and control.

Appropriate use of diagnostic laboratory services to facilitate veterinary medical care is performed. These include gross and microscopic pathology, clinical pathology,
hematology, microbiology, clinical chemistry, and serology. The choice of medication or therapy is made by the veterinarian in consultation with the investigator. The selected treatment plan should be therapeutically sound and, when possible, should cause no undesirable experimental variable.

Subclinical viral, bacterial and parasitic, infections occur frequently in conventionally maintained rodents but also can occur in facilities designed and maintained for production and use of pathogen-free rodents if a component of the microbial barrier is breached. Scientific objectives of a particular protocol, the consequences of infection within a specific strain of rodent, and the adverse effects that infectious agents might have on other protocols in the ARF determine the characteristics of rodent health-surveillance programs and strategies for keeping rodents free of specific pathogens. The principal method for detecting viral infections is serologic testing through the Sentinel Animal Program.

### 7.2.2.1 Sentinel Animal Program

The sentinel animal program consists of quarterly monitoring selected animals for the presence of most common rodent diseases. The program will involve the following procedures:

- Two viral antibody free (VAF) + sentinel animals from Charles River Labs or animals donated from investigators housed in the tested room are placed in co-specific rodent rooms for six to twelve weeks. These individuals are exposed to a composite sample of soiled bedding from other animals in the room at each cage change. One animal of each species are euthanized and tested on arrival to confirm freedom from tested pathogens.
- Blood samples will be collected for serologic testing. When warranted, animals used for disease surveillance should be necropsied to detect diseases that may not be serologically detected.
  - Serum samples will be submitted to RADIL for analysis. The following serologic tests will be considered the basic required tests for each of the species listed: Mice:
    - Mouse Hepatitis Virus (MHV)
    - Sendai Virus (Sendai)
    - Pneumonia Virus of Mice (PVM)
    - Mycoplasma pulmonis
    - Theiler’s Encephalomyelitis Virus (TMEV [GD7])
    - Reovirus-3 (Reo-3)
    - Ectromelia
    - Minute Virus of Mice (MMV)
    - Mouse Parvovirus (MPV)
    - Epizootic Diarrhea of Infant Mice (EDIM – Rotavirus)
    - Lymphocytic Choriomeningitis Virus (LCM)
    - Mouse Norovirus (MNV)
  - Rats:
    - Rat Coronavirus/Sialodacryoadenitis Virus (RCV/SDAV)
    - Sendai Virus (Sendai)
    - Pneumonia Virus of Mice (PVM)
    - Mycoplasma pulmonis
    - Theiler’s Encephalomyelitis Virus (TMEV [GD7])
- Upon detection of antibody titers in sentinel animals, the animal room in question will be placed under quarantine. The quarantine will remain in effect pending a thorough review of the health status of all animals housed within the room and discussion of the known facts and potential implications with the principal investigators. If possible, confirmation of the test result by use of additional tissues (i.e. mesenteric lymph node) and additional serology tests will be performed.

Under no circumstances will animals in a room under quarantine be permitted to be shipped or transferred to other investigators without written authorization from the receiving individual and the attending veterinarian of the facility.

7.2.2.2 Non-serologic Monitoring
While serologic monitoring will detect many of the diseases affecting rodents, other diseases which may be of great importance are not serologically detected. These diseases include ectoparasites, endoparasites, neoplastic diseases, and a variety of bacteriologic diseases. Detection of these diseases requires a nonserologic monitoring program.

Quarterly parasitic examination includes fecal examination, perineal tape test for endoparasites and fur pluck examination for ectoparasites. Once yearly a cecal saline examination for protozoa and nasopharyngeal and cecal bacterial culture is performed.

Gross necropsy examination by a veterinarian of animals used in the sentinel program will be performed at least annually. This examination will include visual evaluation of all internal organs and tissues. Gross necropsies will also be performed on all study animals dying unexpectedly during the project and, if justified, on study animals terminated but not necropsied as a portion of the study. The sentinel program for the LSCDVAMC is performed by the CWRU Animal Resource Center as described in the AAALAC PD.

Tissue histopathology, will be performed when disease conditions warrant further diagnostic testing. Checks for ectoparasites and endoparasites will be made quarterly, on all sentinel animals used for serologic monitoring. Parasitic examination will include a fur pluck or skin scrape external parasites, an adhesive tape check for perianal ova, and a microscopic examination of cecal and proximal colon contents for adult parasites.

Bacteriologic diseases will be detected by culture of the suspect organs of necropsy cases or by PCR amplification of tissue or feces for specific pathogens. Types of cultures obtained and the organs sampled will be dependent upon the judgment of the veterinarian.

7.2.2.3 Health Surveillance Records
It is essential for both colony health-monitoring purposes and for research integrity that records of health surveillance monitoring be maintained.

7.2.3 Clinical Care and Management
Healthy, well cared for animals are a prerequisite for good quality animal based science. Accurate and timely communication of any abnormalities or concerns regarding animal health, behavior, and well being are the responsibility of all that are involved in animal care and research. Emergency care both during and outside of regularly scheduled is required
to maintain a healthy animal program. Medical records are a key element of the veterinary care program and are considered critical for documenting animal wellbeing as well as tracking animal care and use in the ARF.

All USDA regulated species, which include cats and dogs, have medical records that are kept in binders in or near their housing room. These records include all exams, treatments, laboratory test results and specific research procedures. Some investigators may choose to keep duplicate records in their research laboratories. Medical records for any rodent requiring treatment and/or procedures are written on a pink medical record card or, in the case of post surgical rodents, on a blue surgery card, which is placed behind the cage card and is easily visible. Each veterinarian checks all post surgical animals and animals flagged with sick (pink medical record) cards during rounds and updates individual medical records with diagnosis information and treatment requirements.

7.3 Surgery
Appropriate attention to pre-surgical planning, personnel training, aseptic and surgical technique, animal well-being, and animal physiologic status during all phases of a protocol will enhance the outcome of surgery. The individual impact of these factors varies according to the complexity of procedures involved and the species of animal used. A team approach to a surgical project often increases the likelihood of a successful outcome by providing input from persons with different expertise. All surgical procedures must have an approved animal protocol. Surgery can only be performed in an area dedicated for surgery. For rodents this can be a temporary dedication of space that is clean and well delineated. Investigator staff are responsible for cleaning up after themselves in shared spaces.

A continuing and thorough assessment of surgical outcomes is performed to ensure that appropriate procedures are followed and timely corrective changes instituted. Modification of standard techniques might be desirable or even required (for instance, in rodent or field surgery), but it does not compromise the well-being of the animals. In the event of modification, assessment of outcomes should be even more intense and incorporate criteria other than obvious clinical morbidity and mortality.

7.3.1 Presurgical Planning
Includes input from all members of the surgical team, including the surgeon, anesthetist, veterinarian, surgical technicians, animal-care staff, and investigator.

The surgical plan identifies: personnel, their roles and training needs, and equipment and supplies required for the procedures planned; the location and nature of the facilities in which the procedures will be conducted; and preoperative animal-health assessment and postoperative care.

If a non-sterile part of an animal, such as the gastrointestinal tract, is to be surgically exposed or if a procedure is likely to cause immunosuppression, preoperative antibiotics might be appropriate. However, the use of antibiotics does not replace aseptic procedures.

7.3.2 Training
All persons must have had appropriate training to ensure that good surgical technique is practiced, that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns.
People performing and assisting in surgical procedures have a wide range of educational backgrounds and require various levels and kinds of training before they participate in surgical procedures on animals. Thus, training is personalized for each skill set. For example, persons trained in human surgery might need training in inter species variations in anatomy, physiology, and the effects of anesthetic and analgesic drugs, or in postoperative requirements.

The PHS Policy and the AWRs place responsibility with the IACUC for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures to be performed. In Section E of the ACORP, the investigator lists all personnel and their experience level. The IACUC then determines if training is adequate and, if not, recommends additional training for staff. All personnel must complete online training relative to the species used. Personnel who have not previously performed surgery at this VA must review a power point presentation in Rodent or Nonrodent Survival Surgery. During the hands-on orientation process provided by one of the veterinarians, policies for rodent and non rodent surgery are additionally discussed. Anesthesia, analgesia, frequency of post operative care, record-keeping and suture/staple removal are covered. Other experienced staff, investigators or staff veterinarians familiar with the procedure being performed may also provide training specific to the surgical procedure.

7.3.3 Categorization of Surgery
In general, surgical procedures are categorized as major and minor and can be further divided into survival and non-survival. Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation). Minor survival surgery does not expose a body cavity and causes little or no physical impairment (such as wound suturing, peripheral vessel cannulation and percutaneous biopsy). Each survival surgery is reviewed on a case by case basis.

In non-survival surgery, an animal is euthanized before recovery from anesthesia. It might not be necessary to follow all the techniques outlined in this section if non-survival surgery is performed; however, at a minimum, the surgical site should be clipped, the surgeon should wear gloves, and the instruments and surrounding area should be clean.

7.3.4 Aseptic Procedures
Aseptic technique is used to reduce microbial contamination to the lowest possible practical level. No procedure, piece of equipment, or germicide alone can achieve that objective. Aseptic technique requires the input and cooperation of everyone who enters the operating suite. The contribution and importance of each practice varies with the procedure.

Aseptic technique includes preparation of the patient, such as hair removal and disinfection of the operative site; draping of the animal to prevent contamination; preparation of the surgeon such as the provision of decontaminated surgical attire, surgical scrub, and sterile surgical gloves; sterilization of instruments, supplies, and implanted materials; and the use of operative techniques to reduce the likelihood of infection.
7.3.5 Sterilization and Operative facilities
Specific sterilization methods are selected on the basis of physical characteristics of materials to be sterilized. Autoclaving and dry heat sterilization are common effective methods. Sterilization indicators are used to identify materials that have undergone proper sterilization.

Liquid chemical sterilants are used with adequate contact times, and instruments are rinsed with sterile water or saline before use. Alcohol is neither a sterilant nor a high-level disinfectant. Glass bead sterilizers can be used in between animals for surgery to maintain sterility.

In general, unless an exception is specifically justified as an essential component of the research protocol and approved by the IACUC, non-rodent aseptic surgery should be conducted only in facilities intended for that purpose.

Most bacteria are carried on airborne particles or fomites, so surgical facilities are maintained and operated in a manner that ensures cleanliness and minimizes unnecessary traffic. In some circumstances, it might be necessary to use an operating room for other purposes. In such cases, it is imperative that the room be returned to an appropriate level of cleanliness before its use for major survival surgery.

Careful surgical monitoring and timely attention to problems increase the likelihood of a successful surgical outcome. Monitoring includes checking of anesthetic depth and physiologic function and assessment of clinical signs and conditions. Maintenance of normal body temperature minimizes cardiovascular and respiratory disturbances caused by anesthetic agents and is of particular importance.

7.3.5.1 Gas Anesthesia Machine
Anesthesia should only be administered by trained personnel. Each piece of equipment involved in the delivery of inhalant anesthetics should be evaluated regularly to assure its function and integrity. Each person must become familiar with maintenance procedures for the anesthesia equipment that is used. Anesthetic equipment should be checked for leaks before each procedure.

Nosecones must seal tightly around the patient's nose to avoid leaks and must be small enough to eliminate dead space. If you are using masks with large amounts of dead space, sufficient fresh gas delivery can be accomplished by increasing the oxygen flow rate, but increased flows may lead to increased trace gas exposure.

7.3.5.1.1 Scavenging
A scavenging system consists of a gas collecting device (e.g., a scavenging pop-off or overflow valve), transfer tubing, an interface, additional transfer tubing, and a gas disposal system. Passive systems that simply vent gases to floor level and rely on inhalant anesthetic gases being heavier than air are unacceptable.

Non-recirculating room-ventilation systems, which provide 12 to 15 air changes/hour, can be used for waste-gas disposal by routing transfer tubing to an exhaust grille. Masks with activated charcoal filters can be used by personnel who are at special risk (e.g., pregnancy).
Activated charcoal canisters vary in effectiveness with different brands and with changes in the rate of gas flow through the canister. Activated charcoal is not effective for absorption of nitrous oxide. The scavenging system should be properly attached at all connectors. The appropriate vacuum should be assured for active systems. If charcoal canisters are employed for scavenging, they should be changed at appropriate intervals, according to the directions of the manufacturer.

7.3.5.1.2 Exposure and Monitoring
Intermittent low level exposure of personnel to inhalant anesthesia gases has been linked to increased incidence of spontaneous abortions as well as decreased fertility in women. ACGIH is The American Conference of Industrial Hygienists (ACGIH) and the Occupational Safety and Health Administration (OSHA) with guidance from the National Institute for Occupational Safety and Health (NIOSH) has recommended that:

- When halogenated agents are used alone, exposure should be limited to 2 parts per million (ppm) based on a 1 hour sample
- When halogenated agents are used in combination with nitrous oxide, exposures should be limited to 0.5 ppm for halothane and other volatile anesthetics and 25 ppm for nitrous oxide
- When nitrous oxide is used alone, exposures should be limited to 25 ppm

Safety can perform air monitoring to determine the anesthetic gas concentrations in the air. Personal monitoring is conducted at the employee's breathing zone to determine waste anesthetic gas exposure for the employee. The monitoring is performed using a passive dosimeter which collects gas on a media and is then analyzed by a laboratory. Most facilities opt to have one person in each procedure area wear a badge once every six months.

The Safety committee may opt for more frequent monitoring if results exceed personal exposure limits, procedure protocols change, if there is a change in personnel or equipment, or as needed. Area monitoring is conducted in the work area to give waste anesthetic gas concentrations in work areas. A portable infrared spectrophotometer, or direct read instrument, is used to collect real time samples. Safety can also perform leak testing on the equipment to determine if gas is escaping from various locations in the machine. A portable infrared spectrophotometer is used to detect leakage.

7.3.5.1.3 Operating Instructions
1. **Inspect.** Always inspect the tubing, connections and other parts before beginning any procedure.

2. **Oxygen.** Connect the green oxygen line from the house line to the regulator. If the house oxygen is not available, connect a small green oxygen tank to the regulator (these tanks will last about 2 hours with continuous use, so be sure to have a spare on hand if necessary).
3. **Fill.** Check the level of isoflurane on the vaporizer, the level should be between the white arrows. NEVER fill while the unit is on, turn the vaporizer to 0 or OFF before refilling!!

4. **Vacuum.** Connect the clear vacuum line to the chamber (upper port of the chamber) and the house line. Connect the white vacuum line to the splitter on the other house line, this hose is for open scavenging and can be secured to the surgical scope to catch possible leaks near the surgeon.

4a. **Scavenger.** At this time, the vacuum attached to the scavenging unit is too strong and prevents anesthetic from reaching the animal. If this happens, use a charcoal filter supplied by VetEquip attached to the larger tubing coming from the nose cone. Record the weight of the filter before each use and replace it when it has increased total weight by 50 grams. The VetEquip filters are better at filtering excess isoflurane, but f/air canisters can be used if necessary (NOTE: do not place an f/air canister on its side).
5. **Chamber.** Be sure that the clear vacuum line is connected to the upper port on the induction chamber, and the black tube coming from the mobile cart is connected to the lower port on the chamber. It is recommended to use a heating pad under the induction chamber. It is helpful to cut a piece of clean absorbent pad to place in the chamber for the animals. This will make clean-up easier and keep the animals warmer.

6. **Nose Cone.** The 2009 unit comes with 3 nose cones (small for mice, medium for small rats, and large for larger rats) and a stereotaxic adapter. The stereotaxic set up is very similar. The O2 & Isoflurane flow from the line on the left through the nose cone and exit on the right through the charcoal scavenger. Clean the nose cone and tubing that will be on the surgical table with Clidox before & after your procedure (do not use alcohol or ammonia).
7. **Stopcocks.** Turn the stopcock for the nose cone OFF, and for the chamber ON.
8. **Flow rate.** Set the oxygen flowmeter to 1 liter per minute (lpm). The flow rate is 1.5 lpm if both stopcocks are ON.

9. **Induction.** Place animal #1 in the induction chamber and secure the lid. Turn the vaporizer dial to 2.5-3%. The animal should be non-responsive in about 3 minutes. Always watch the animal’s breathing while in the chamber.

10. **Begin.** Slowly open the chamber and remove animal #1. Do not place your face near the open chamber and close the chamber immediately after removing the animal. Open the stopcock to the nose cone line and place animal #1 in the nose cone. You can use a loop of suture to hook the animal’s incisors and secure its snout. Rodents are obligate nose breathers, so it is not necessary to have more than their nose in the cone.

11. **Increase flow rate.** If both stopcocks are at the ON position to the chamber and the nose cone, change the flow rate to 1.5 lps. This may require adjusting the isoflurane level.
If the animal starts breathing short, shallow breaths decrease the vaporizer level by 0.5% increments.

12. **Oxygen flush.** If necessary, you can perform an oxygen flush to give the animals a blast of oxygen. This is usually effective if their breathing becomes too depressed. It will not awaken the animal. Always check the nose cone after a flush, as the nose may get pushed out.

13. **Prepare 2nd animal.** Place animal #2 in the chamber.

14. **Recovery.** When the procedure on animal #1 is complete, close the stopcock to the nose cone line and place the animal in a recovery unit. Ensure a warm and escape proof recovery unit.

Repeat until all procedures are complete.

### 7.3.5.1.4 Clean Up

Never use alcohol or ammonia to clean the chamber. Soap and water followed by Clidox is recommended. If you used an absorbent pad, remove it and wipe out the chamber then spray Clidox and leave it to air dry. Unhook the hoses from the ceiling house lines for the vacuum and oxygen. Clean the nose cone with Clidox and leave it in the drawer of the anesthesia unit.

### 7.3.6 Post Surgical Monitoring and Record Keeping

Pre-surgical planning specifies the requirements of postsurgical monitoring, care, and record-keeping, including the personnel who will perform these duties. The investigator and veterinarian share responsibility for ensuring that postsurgical care is appropriate.

An important component of postsurgical care is observation of the animal and intervention as required during recovery from anesthesia and surgery. The intensity of monitoring necessary will vary with the species and the procedure and might be greater during the immediate anesthetic recovery period than later in postoperative recovery.

During the anesthetic-recovery period, the animal is in a clean, dry area where it can be observed often by trained personnel. Particular attention is given to thermoregulation, cardiovascular and respiratory function, and postoperative pain or discomfort during recovery from anesthesia.

Additional care might be warranted, including administration of parenteral fluids for maintenance of water and electrolyte balance, analgesics, and other drugs; care for surgical incisions; and maintenance of appropriate medical records.

After anesthetic recovery, monitoring is often less intense but includes attention to basic biologic functions of intake and elimination and behavioral signs of postoperative pain, monitoring for postsurgical infections, monitoring of the surgical incision, bandaging as appropriate, and timely removal of skin sutures, clips, or staples.

Records must be kept of all surgical procedures done in all animals. These records must be individual records for each animal. They must include animal number, species, date of
the procedure, time of administration of all drugs (includes anesthetics and analgesics),
time of the procedure, type of procedure, evidence of intra-operative monitoring (e.g. color
of mucous membranes, heart rate, respiratory rate, response to toe pinch, blood pressure,
etc), time of the end of the procedure, evidence of post-operative monitoring, time of last
monitoring and condition of patient when monitoring stopped (e.g., sternal recumbancy).

In the ACORP, the frequency of intra-operative and post-operative monitoring is stated.
Records must be kept with the animal; however a copy may also be kept in investigator’s
laboratory. Part of the ongoing veterinary medical care program and post approval
monitoring is centered on knowing what has happened in any potentially sick animal.

7.4 Handling and Special Animal Procedures
7.4.1 Animal Handling
7.4.1.1 Rats
Pick up by grasping the base of the tail for transfer to a new location. Do not permit the rat
to dangle. Cup the hand over the back with the thumb just behind the forelegs and the
fingers behind the head. Use this method for restraint to inspect or inject. Clean restraint
gloves or a clean surgical towel may be used for these procedures, though in most
instances they are unnecessary.

7.4.1.2 Mice
Pick up by grasping the base of the tail. Do not permit the animal to dangle. To restrain, set
the animal on the cage top while holding the tail, then grasp the loose skin of the dorsal
neck and back using the other hand. Slide the tail under the last finger of the restraining
hand and hold down. This leaves one hand free to inspect or inject.

7.4.1.3 Rabbits
Pick up by grasping the loose skin on the neck and back while supporting the hindquarters
with the other hand. For extensive transport, use a “football carry.” Tuck the head under
the handler's arm at the elbow. Press the body and rear end against the waist with the arm,
supporting the body, and the hand under the rabbit's rear. NOTE: NEVER LIFT A RABBIT
BY ITS EARS
7.4.1.4 Dogs and Cats
Lift in the crook of the arms. This is accomplished by placing one arm around the animal's chest and supporting the trunk and hindquarters with the other arm.

7.4.2 Blood Collection
Both the quantity and frequency of blood sampling is dependent on the circulating blood volume of the animal. For a single or multiple survival collection: If you require more than 10 ml blood/kg body weight, a scientific justification is required in advance for IACUC review and approval.

For a single collection followed by immediate euthanasia: If you require more than 35% of an animal’s blood volume (this is based on a human calculation for allowable blood loss for which a range of 20 – 43% is acceptable blood loss depending on the starting hematocrit), the animal must be anesthetized for the procedure followed by humane euthanasia. If anesthesia cannot be used, a scientific justification is required in advance for IACUC review and approval.

For fasting samples, deprive the animals of food for at least 8 hours prior to blood collection. When collecting blood from rodents, use a heat to gently warm the area to facilitate blood flow. Use appropriate restraint measures. It is mandatory to use anesthesia when collecting blood from the femoral vein, femoral artery, vena cava, orbital plexus and for the retro orbital bleeding technique and cardiac puncture. Investigators are reminded that they may be granted an exemption from this policy if they request it in writing, and provide valid scientific reasons why anesthesia will interfere with the proposed study results. If a syringe and needle are used to collect blood always remember to apply direct pressure to the puncture site for hemostasis.

7.4.3 Tail Clipping in Rodents
Tail clipping on mice and rats without anesthesia can be performed only once on each said species up to 17 days of age, removing no more than 0.5 cm of the tail. Anesthesia is required if the animal is over 17 days of age, more than 0.5 cm of tail is removed, and/or when the procedure must be repeated. Technician performing the tail clipping must ensure that the any bleeding has stopped prior to returning the animal to its cage. Hemostasis can be achieved by compression, cauterization or by chemical astringents (silver nitrate).

7.4.4 Antibody Production
7.4.4.1 Polyclonal Antibody Production
7.4.4.1.1 Adjuvants
There are a number of adjuvants of interest to the IACUC. Freund's Complete Adjuvant (FCA) is of particular interest because it can cause severe inflammation and ulceration at
the injection site if used incorrectly. FCA should be used only for the initial immunization, with Freund’s Incomplete Adjuvant (FIA) used for subsequent booster injections. Other adjuvants should be considered, before FCA and FIA is used. FCA should only be used if no appropriate alternatives are available. It is necessary to provide the specific rationale for selection of species and adjuvant for use with particular antigens. Applications must be based on consideration of the amount of antibody required, the type of response required, and the nature of the antigen.

7.4.4.1.2 Freund’s Adjuvant
FIA consists of 85% mineral oil or paraffin oil and 15% mannide monooleate (Arlacel A) as emulsifier. With the addition of heat-killed mycobacteria (M. butyricum or M. tuberculosis) the mixture is termed FCA. FCA is known to commonly produce undesirable side effects. Negative effects routinely seen include granuloma formation, tissue necrosis and sloughing, abcessation, and fever. Other deleterious systemic effects, such as polyarthritis, have been reported. FCA is considered a human biohazard, with accidental self-innocation, or eye splash have been shown to cause painful sequelae not readily amenable to treatment, as well as sensitization to tuberculin.

7.4.4.1.3 Other Adjuvants
Less inflammatory alternatives to Freund’s adjuvant are available and should be considered. Ribi Adjuvant System® and TiterMax® are commonly cited as appropriate alternatives. Noninflammatory adsorptive adjuvants such as alum and aluminum hydroxide gel may also be considered.

7.4.4.1.4 Routes of Administration, Volume Sites and Species Selection
Consideration and justification must be given in the animal use protocol for selection of the laboratory animal species, adjuvant, volume per injection site, site of administration, number of sites, and response required. Particularly with the use of Freund’s adjuvant, it is important to note that the severity of potentially painful inflammatory reactions may be minimized by injection of a small volume of inoculum per site and the use of multiple, sufficiently separated, injection sites when appropriate. The table below lists the recommended maximum volumes of antigen when using Complete Freund’s Adjuvant. Routes of administration include:

- Intramuscular (IM)
- Subcutaneous (SC)
- Intradermal (ID)
- Intraperitoneal (IP) – only recommended in rodents and requires additional justification because of the generalized vs. localized inflammatory reaction initiated
- Intravenous (IV) may be acceptable only if injecting soluble antigens without adjuvant.

<table>
<thead>
<tr>
<th>Species</th>
<th>SC</th>
<th>ID</th>
<th>IP</th>
<th>IM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>&lt; 0.1 ml</td>
<td>&lt; 0.05 ml/ site**</td>
<td>&lt; 0.2 ml</td>
<td>&lt; 0.05 ml**</td>
</tr>
<tr>
<td>Rat</td>
<td>&lt; 0.1 ml</td>
<td>&lt; 0.05 ml</td>
<td>&lt; 0.5 ml</td>
<td>&lt; 0.1 ml**</td>
</tr>
<tr>
<td>Rabbit</td>
<td>&lt; 0.25 ml</td>
<td>&lt; 0.05 ml</td>
<td>*</td>
<td>&lt; 0.25 ml***</td>
</tr>
</tbody>
</table>

* Not Recommended
** Must be justified
*** Only one limb recommended unless justified
7.4.4.1.5 Frequency of Boosters
The frequency of boosters must be addressed in the ACORP. Two to three weeks is generally considered the minimum time period between the initial and subsequent immunizations. Booster immunizations are sometimes delayed if significant inflammatory reactions are still present from the initial immunization. Booster immunizations cannot use Complete Freund’s adjuvant.

7.4.4.1.6 Evaluation of Pain and Distress
It is the PI’s responsibility to ensure the animals are regularly checked in addition to the daily checking done by animal care technicians. The animals should be observed for evidence of pain or distress, and for evidence of lesions such as swelling, abscess or fistula formation, and infection or ulceration at the immunization sites. The animal weight should periodically be compared to initial animal weights and this should be indicated in the protocol and documented. Veterinary follow-up must include clinical observations and palpations of the injected sites and determination of the appropriate supportive therapy.

7.4.4.1.7 Blood Collection Guidelines
The general guideline for collection of blood from any healthy research animal without causing anemia is 9 ml/kg of body weight once monthly. This amount is reduced to 6 ml/kg for collection every two weeks and to 3 ml/kg for collection once every week. When multiple sequential blood collections are to be made, the animal’s hematocrit must be checked at least once a month to evaluate the animal for the anemia development.

7.4.4.1.7.1 Maximum Blood Collection Volumes and Frequency for Rabbits
Listed below are specific blood collection amounts recommended to facilitate collection of safe amounts of blood in rabbits that have historically been shown to preclude the development of anemia in healthy research rabbits.

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Blood Volume (ml)</th>
<th>Once/week</th>
<th>Every 2 weeks</th>
<th>Once/month</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>168</td>
<td>13 ml</td>
<td>17 ml</td>
<td>26 ml</td>
</tr>
<tr>
<td>3.5</td>
<td>196</td>
<td>15 ml</td>
<td>20 ml</td>
<td>30 ml</td>
</tr>
<tr>
<td>4.0</td>
<td>224</td>
<td>17 ml</td>
<td>22.5 ml</td>
<td>34 ml</td>
</tr>
<tr>
<td>4.5</td>
<td>252</td>
<td>19 ml</td>
<td>25 ml</td>
<td>38 ml</td>
</tr>
<tr>
<td>5.0</td>
<td>280</td>
<td>21 ml</td>
<td>28 ml</td>
<td>42 ml</td>
</tr>
<tr>
<td>5.5</td>
<td>308</td>
<td>23 ml</td>
<td>31 ml</td>
<td>46 ml</td>
</tr>
<tr>
<td>6.0</td>
<td>336</td>
<td>25 ml</td>
<td>34 ml</td>
<td>50 ml</td>
</tr>
</tbody>
</table>

7.4.4.2 Monoclonal Antibody Production in Mice by Ascites
The production of monoclonal antibodies is a two step process. First, an animal (usually a mouse) is immunized to generate antibody producing cells which are fused with a tumor cell line. The second step is to perpetuate the antibody secreting cells either in culture, or by injection into the peritoneum of mice to yield ascites. From an animal welfare standpoint in vitro methods of monoclonal antibody production are preferable. Evidence must be presented in the protocol that in vitro methods are not acceptable for the production of the monoclonal antibodies required for the research study, before the use of the mouse ascites method can be approved. All hybridoma cells must be tested prior to their use to confirm the absence of pathogenic agents. MAP testing, PCR testing or some other test for pathogens must be performed.
7.4.4.2.1 Immunization
The guidelines listed in the preceding section for polyclonal antibody production apply to
the immunization in the first step for production of sensitized cell colonies for monoclonal
antibody production. These animals are euthanized and spleens are harvested for selection
of specific cell colonies for hybridoma formation.

7.4.4.2.2 Priming Agent
Pristane is the agent most frequently used to "prime" the peritoneal cavity for successful
growth of hybridomas as ascites producing tumors. The smallest volume of the priming
agent causing minimal distress and yielding ascites producing tumors should be used. 0.25
ml or less per mouse is recommended. The priming agent selected and volume injected, or
other methods or procedures used to enhance production of ascites fluid (e.g., irradiation),
must be justified in the protocol.

7.4.4.2.3 Inoculation of Hybridoma Cells
Inoculation will be done by standard intraperitoneal injection. Animals are injected with
hybridoma cells about 7-14 days after priming. Cell numbers and volume of fluid injected
should be minimized to elicit as few ascitic tumors as possible. This range varies with the
cell line being used. Pilot studies are often required to determine optimal cell numbers for
best response.

7.4.4.2.4 Abdominal Paracentesis
Ascites pressure must be relieved by abdominal paracentesis when visible abdominal
distention becomes evident, and prior to the development of marked abdominal distention
with associated clinical signs of pain or distress. It is recommended that anesthesia be
used and that the needle insertion site is antisepically prepared.

The smallest gauge needle feasible for the extraction of the viscous fluid should be used.
The volume of ascites fluid removed should not exceed 3 ml/collection. If this volume is
greater than the total blood volume of a mouse and physiologic distress from hypovolemia
can result. To help prevent hypovolemic shock, 2-3 ml of warm saline or lactated ringers
solution may be administered subcutaneously between the shoulder blades of the mouse
immediately following paracentesis.

Collections of ascites should be limited to a maximum of 2 collections per animal, with the
last one being a terminal procedure, with collection after euthanasia. Intervals of 1-3 days
between taps are recommended depending upon the degree of abdominal distention.
Animals must be weighed daily. This should begin prior to tapping and continue until
euthanasia. The tumor mass must not exceed 15% of the animal’s body weight after the
animal has been tapped.

7.4.4.2.5 Clinical Observation
Animals must be observed daily after hybridoma cell injection, including weekends and
holidays, to monitor the degree of abdominal distension, to relieve it as needed, and to look
for other signs of illness. The laboratory staff is responsible for daily checks but upon
request the ARF staff may conduct these observations on the weekend.

Fluid should be removed before abdominal distension is great enough to cause discomfort,
labored breathing, or to interfere with normal activity. Fluid removal is done by insertion of a
needle into the abdominal cavity. The smallest needle possible (18-23 gauge) should be used for harvest.

Ascites fluid may be harvested only once with recovery of the animal. After the initial fluid harvest the mice must be observed twice daily by laboratory staff. Ascites fluid should not exceed 20% of the baseline body weight.

After harvesting, the mouse is particularly sensitive to shock. Animals should be monitored over the next several hours following the tap for pale eyes, ears and muzzle, and breathing difficulties. Saline (2-3mls) may be given subcutaneously if shock develops.

If animals exhibit severe clinical abnormalities or become moribund, they should be euthanized. Death is not considered an acceptable endpoint to the experiment.

7.4.5 Endpoint Criteria
The humane endpoint criteria include five areas of observation: body weight, physical appearance, measurable clinical signs, unprovoked behavior and response to stimulus. The following table indicates that observations that should be made in each of these categories and criteria that would warrant consideration of humane euthanasia. Daily observations should be made as part of the daily care records for animals.

Humane endpoints should additionally be tailored to each described experimental procedure and include potential adverse outcomes that may occur.

<table>
<thead>
<tr>
<th>Category</th>
<th>Observation</th>
<th>Humane Endpoint Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Weight</td>
<td>Body Weight</td>
<td>&gt;25% weight loss over a 7 day period</td>
</tr>
<tr>
<td></td>
<td>Food/water consumption</td>
<td>Anorexia for &gt;72 hours</td>
</tr>
<tr>
<td>Appearance</td>
<td>Coat Condition</td>
<td>Poor coat condition, absence of grooming</td>
</tr>
<tr>
<td></td>
<td>Posture</td>
<td>Persistent “hang dog” posture</td>
</tr>
<tr>
<td>Clinical Signs</td>
<td>Respiration</td>
<td>Persistently labored</td>
</tr>
<tr>
<td></td>
<td>Tremors</td>
<td>Continuous tremor</td>
</tr>
<tr>
<td></td>
<td>Convulsions</td>
<td>&gt; 10 minutes in duration</td>
</tr>
<tr>
<td></td>
<td>Prostration</td>
<td>&gt;2 hours</td>
</tr>
<tr>
<td>Unprovoked Behavior</td>
<td>Socialization</td>
<td>No peer interaction</td>
</tr>
<tr>
<td>Response to Stimulus</td>
<td>Provoked Behavior</td>
<td>Unresponsive to extraneous activity or stimulation</td>
</tr>
</tbody>
</table>

7.5 Pain, Distress, Analgesia and Anesthesia
An integral component of the veterinary medical care program is prevention or alleviation of pain associated with procedural and surgical protocols.

Pain is a complex experience that typically results from stimuli that damage tissue or have the potential to damage tissue. The ability to experience and respond to pain is widespread in the animal kingdom. A painful stimulus prompts withdrawal and evasive action. Pain is a stressor and, if not relieved, can lead to unacceptable levels of stress and distress in animals.
The proper use of anesthetics and analgesics in research animals is an ethical and scientific imperative. Recognition and Alleviation of Pain and Distress in Laboratory Animals (NRC, 1992) is a source of information about the basis and control of pain. Fundamental to the relief of pain in animals is the ability to recognize its clinical signs in specific species. Species vary in their response to pain, thus criteria for assessing pain in various species differ. Some species-specific behavioral manifestations of pain or distress are used as indicators, for example, vocalization, depression or other behavioral changes, abnormal appearance or posture, and immobility. It is therefore essential that personnel caring for and using animals be very familiar with species-specific (and individual) behavioral, physiologic, and biochemical indicators of wellbeing.

In general, unless the contrary is known or established it should be assumed that procedures that cause pain in humans also cause pain in animals.

7.5.1 USDA Pain Categories
Because the USDA classification system is based on the “potential for pain, distress or discomfort,” the anesthetic/euthanasia drug dose becomes a critical concern. (Note: There is no USDA Category A)
- Level B: Breeding or Holding Colony Protocols
- Level C: No more than momentary or slight pain or distress. For example: euthanized for tissues; just observed under normal conditions; positive reward projects.
- Level D: Pain or distress relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress. For example: survival surgery, non-survival surgery, induced infections or antibody production with appropriate anesthesia and post-op/post-procedure analgesia when necessary.
- Level E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.

7.5.2 Analgesia and Anesthesia
The selection of the most appropriate analgesic or anesthetic reflects professional judgment as to which best meets clinical and humane requirements without compromising the scientific aspects of the research protocol.

Preoperative or intraoperative administration of analgesics might enhance postsurgical analgesia.

The selection depends on many factors, such as the species and age of the animal, the type and degree of pain, the likely effects of particular agents on specific organ systems, the length of the operative procedure, and the safety of an agent for an animal, particularly if a physiologic deficit is induced by a surgical or other experimental procedure. Such devices as precision vaporizers and respirators increase the safety and choices of inhalation agents for use in rodents and other small species.

Some classes of drugs—such as sedatives, anxiolytics, and neuromuscular blocking agents—are not analgesic or anesthetic and thus do not relieve pain; however, they might be used in combination with appropriate analgesics and anesthetics.
Neuromuscular blocking agents (e.g., pancuronium) are sometimes used to paralyze skeletal muscles during surgery in which general anesthetics have been administered. When these agents are used during surgery or in any other painful procedure, many signs of anesthetic depth are eliminated because of the paralysis. However, autonomic nervous system changes (e.g., sudden changes in heart rate and blood pressure) can be indicators of pain related to an inadequate depth of anesthesia. If paralyzing agents are to be used, it is recommended that the appropriate amount of anesthetic be first defined on the basis of results of a similar procedure that used the anesthetic without a blocking agent.

In addition to anesthetics, analgesics, and tranquilizers, non-pharmacologic control of pain is often effective.

Neuromuscular blocking drugs, as noted earlier, do not provide relief from pain. They are used to paralyze skeletal muscles while an animal is fully anesthetized. They might be used in properly ventilated conscious animals for specific types of non-painful, well-controlled neurophysiologic studies. However, any such proposed use is carefully evaluated by the IACUC to ensure the well-being of the animal because acute stress is believed to be a consequence of paralysis in a conscious state and it is known that humans, if conscious, can experience distress when paralyzed with these drugs.

7.6 Euthanasia
Euthanasia is the act of killing animals by methods that induce rapid unconsciousness and death without pain or distress. Unless a deviation is justified for scientific or medical reasons, methods should be consistent with the 2007 Report of the AVMA Panel on Euthanasia or most current version.

In evaluating the appropriateness of methods, some of the criteria that should be considered are ability to induce loss of consciousness and death with no or only momentary pain, distress, or anxiety; reliability; non-reversibility; time required to induce unconsciousness; species and age limitations; compatibility with research objectives; and safety of and emotional effect on personnel.

Euthanasia might be necessary at the end of a protocol or as a means to relieve pain or distress that cannot be alleviated by analgesics, sedatives, or other treatments.

Protocols should include criteria for initiating euthanasia, such as degree of a physical or behavioral deficit or tumor size, which will enable a prompt decision to be made by the veterinarian and the investigator to ensure that the end point is humane and the objective of the protocol is achieved.

Euthanasia should be carried out in a manner that avoids animal distress. In some cases, vocalization and release of pheromones occur during induction of unconsciousness. For that reason, other animals should not be present when euthanasia is performed.

The selection of specific agents and methods for euthanasia depend on the species involved and the objectives of the protocol. Generally, inhalant or non-inhalant chemical agents (such as barbiturates, non-explosive inhalant anesthetics, and CO2) are preferable to physical methods (such as cervical dislocation, decapitation, and use of a penetrating captive bolt). However, scientific considerations might preclude the use of chemical agents
for some protocols. All methods of euthanasia should be reviewed and approved by the IACUC.

It is essential that euthanasia be performed by personnel who are skilled in methods for the species in question and that it is performed in a professional and compassionate manner. Death should be confirmed by personnel who can recognize cessation of vital signs in the species being euthanized. When using anesthetics or CO2 euthanasia techniques, a secondary method such as cervical dislocation is required to ensure the death of the animal.

Euthanizing animals is psychologically difficult for some animal-care, veterinary, and research personnel, particularly if they are involved in performing euthanasia repetitively or if they have become emotionally attached to the animals being euthanatized. When delegating euthanasia responsibilities, supervisors should be aware of this as a potential problem for some employees or students.

7.6.1 Chemical Method
7.6.1.1 Injection
Following chemical euthanasia, a physical method is usually required to ensure death. Verification of death must be completed by an approved and appropriately trained individual. Prolonged absence of heart beat, respirations and voluntary body movements are reliable indicators of death.

Dogs and cats are given an overdose via IV or IC of Sodium Pentobarbital. Rodents and rabbits are given an IC, IP or IV overdose of Sodium Pentobarbital.

7.6.1.2 Carbon Dioxide (CO2)
For euthanizing rodents, CO2 gas inhalation is one of the most common methods. Euthanasia must be performed by trained personnel to ensure death as quickly and painlessly as possible. When using CO2, a secondary (physical) method such as cervical dislocation or opening of the chest cavity must be performed to complete the procedure. Euthanasia must be performed in the necropsy room.

If euthanizing an entire cage of rodents, transport the rodents in the cage with the isolator top in place. If euthanizing selected animal(s) from a group, place the animal(s) in a clean cage with a wire bar lid and filter top. Adjust the quantity on the cage card of the remaining animals. Upon leaving the animal room, record the number of animals to be euthanized under the correct column on the census sheet.

Take the caged animals to the necropsy and place them in the euthanasia chamber (if the cage fits without filter top leave animals in the cage, if not place the animals directly in the chamber). DO NOT OVERCROWD THE CHAMBER. With gas hose in place, turn on the CO2, and let the gas run slowly until the animals cease to breathe. Leave the animal sealed in the CO2 chamber for a minimum of 5 minutes or until the animal has expired. NOTE: newborn animals need less oxygen, therefore euthanasia will take up to 30 minutes.

Ensure the death of the animals by using a secondary method such as cervical dislocation or cutting open the chest cavity. Place the dead animal(s) in a carcass bag and place in the
cold room. Clean euthanasia chamber and counter with Clidox when finished. Be sure CO₂
tank is shut of prior to leaving the room.

7.6.2 Physical Methods
7.6.2.1 Cervical Dislocation
This method is primarily reserved for euthanasia of mice and neonatal rats. Manual
cervical dislocation is a humane technique for euthanasia of mice and rats weighing <200 g
and rabbits weighing <1 kg when performed by individuals with a demonstrated high
degree of technical proficiency. It is strongly advised that anesthesia be used prior to use of
any physical method. Exceptions must be approved with scientific justification in the
ACORP and documentation of expertise.

7.6.2.2 Decapitation
This procedure is for use in rodents and should only be performed by experienced
personnel. It is to be used when no other method of euthanasia is suitable (e.g., for
collection of tissues or body fluids that are chemically uncontaminated). The animal should
be anesthetized prior to conducting the procedure unless scientific justification has been
provided and approved in the ACORP.

All decapitators are the personal property of each individual investigator and therefore the
maintenance is the responsibility of the owner. Log books should be kept with the device
and updated with use and routine maintenance. Sharpening of the blades must be
performed at least once yearly. The blade movement should be smooth with no perceptible
binding or resistance. The blade must be rust free, clean, and sharp and decapitate with
minimal force.

7.6.2.3 Exsanguination
This procedure is to be used only in fully anesthetized animals when a large volume of
blood/plasma/serum must be collected terminally from the animal. Once the animal is
anesthetized, incise a large superficial blood vessel (e.g., jugular vein) or use cardiac
puncture to collect the required volume of blood. Note: sufficient volumes of blood must be
collected to irreversibly cause hypovolemic shock in the animal and therefore death.

7.7 Drug Use, Storage and Control
7.7.1 Use of Expired Drugs and Medical Supplies
The USDA’s Animal Care Policy Manual states: “The use of expired medical materials such
as drugs, fluids, or sutures on regulated animals is not considered to be acceptable
veterinary practice and does not constitute adequate veterinary care as required by the
regulations promulgated under the Animal Welfare Act. All expired medical materials found
in a licensed or registered facility are to be brought to the attention of the responsible
official. The facility must either dispose of all such materials or segregate them in an
appropriately labeled, physically separate location from non-expired medical materials.”

The use of expired drugs in research animals is deemed an unacceptable threat to animal
welfare and an unacceptable threat to the study’s scientific validity; therefore, all research
staff should check their inventory of drugs and supplies on a monthly basis.
All expired items, except controlled substances, must be discarded. Controlled substances that are expired should be returned to pharmacy along with the tracking sheet and a replacement obtained.

Expired supplies (e.g. suture materials) may only be used in acute terminal procedures. Expired supplies to be used in acute terminal procedures must be labeled and stored in a physically separate location from non-expired medical materials. Any expired items not used in animals must be clearly marked “FOR IN-VITRO USE ONLY- NOT FOR USE IN ANIMALS”. If expired items are not clearly marked, the IACUC will assume it is being used in animals and act as stated in this policy.

Any rooms listed on an approved protocol will be thoroughly inspected by the IACUC at least every 6 months. The IACUC inspection team may inspect all cabinets, drawers, and other storage units in the room. Upon finding recurring deficiencies regarding this policy, the IACUC may request the PI to explain to the IACUC at a convened meeting why expired items were discovered in their laboratory and take appropriate action.

7.7.2 Use of Pharmaceutical Grade Drugs in Vertebrate Animals
Pharmaceutical grade drugs are to be used for all vertebrate species based on the Public Health Service Policy (PHS Policy) and the United States Department of Agriculture (USDA) regulations. The use of non-pharmaceutical grade chemical compounds in experimental animals (including rats and mice) under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research. Their use should be based on:
- Scientific necessity
- Non-availability of an acceptable pharmaceutical grade product
- Specific review and approval by the IACUC

In preparing and reviewing proposals to use non-pharmaceutical grade products, investigators and IACUCs consider a number of related animal welfare and scientific factors including safety, efficacy, and the inadvertent introduction of research complicating variables. While issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control are assumed to have been addressed during the course of producing pharmaceutical grade drugs, the same cannot always be said for substances produced in the research laboratory using non-pharmaceutical grade chemical compounds (e.g. saline, glucose, etc.). Cost savings alone is not an adequate justification for using nonpharmaceutical compounds in animals (e.g. chemical grade Pentobarbital, etc.).

Although the potential animal welfare consequences of complications are less evident in nonsurvival studies, the scientific issues remain the same. The principles and need for professional judgment outlined above still apply. The use of non-pharmaceutical grade drugs in vertebrate species must be explicitly detailed in the IACUC protocol and IACUC approval gained prior to use of the drug. Reconstituted drug (vial) label must include the date of reconstitution and expiration date in order to assure timely disposal of the drug.

7.7.3 Controlled Substance Storage and Use
Controlled substances are locked within the ARF surgical suite. Pharmacy service monitors the use of and tracking for controlled substances and Police Service audits to verify if
recordkeeping accounts for the amount of drug on hand on a monthly basis. The IACUC verifies that all drugs are stored correctly and in date during its semi-annual inspections.

Multi-Dose Vials: All multi-dose vials will be dated/initialed by the staff opening them with the date of the first use and the appropriate expiration date, as indicated below. The multi-dose vials will be discarded when the earliest instance of the following occurs:

- 28 days after opening the vial (or sooner if specified by the manufacturer)
- the vial is empty
- suspected or visible contamination occurs
- the manufacturer’s expiration date is reached for unopened vials

If it is necessary to dilute a controlled substance, compound it with other substances, or transfer into a container other than the original bottle, the following guidelines must be followed:

- The diluted or transferred product should be marked with the name of the drug, expiration date, mix date and initials of technician.
- Drugs for parenteral use must be diluted and/or transferred aseptically (i.e. dilutes with sterile saline or sterile water into a sterile vial using sterile transfer equipment) and used within 60 days or less based on the expiration date of the diluted substance. It is not necessary to handle drugs for oral administration aseptically; however, drugs which are mixed with food or fluid for oral administration should be refrigerated and used within 28 days or less based on the stability of the compounded substance. These diluted products must be clearly labeled as specified above.

7.7.4 Administration of Drugs

Drugs should be administered only as part of an approved research protocol or as prescribed by the veterinarian. Proper administration requires:

- Knowledge of the anatomy of the injection site
- Knowledge of the properties of the drug
- Knowledge of potential discomfort/pain because of the location/method of administration

Drugs can be administered:

- Per Os: through the mouth and is used for tablets, capsules and boluses
- Per Rectum: into the rectum and is used for liquids and suppositories
- Gavage: into the stomach and is used for liquids
- Intravenous (IV): into a vein and is used for sterile liquids for survival procedure
- Intraparenteral (IP): into the abdominal cavity and is used for sterile liquids for survival procedure
- Subcutaneous (SC): under the skin and is used for sterile liquids, tablets or gels for survival procedure
- Intramuscular (IM): into a muscle and is used for sterile liquids for survival procedures
- Intradermal (ID): into the layers of the skin and is used for sterile liquids for survival procedures
- Intrathecal (IT): into the subarachnoid space of the spinal cord and is used for sterile liquids for survival procedures
- Intracranial (IC) into the brain and is used for sterile liquids for survival procedures
- Topical is onto the surface and is used for liquids, ointments, crèmes, and powders
References


Louis Stokes Cleveland Veterans Affairs Medical Center Policy 151-003. (2010). *Protection of Animal Subjects in Research*.


ACUP SOP Appendix 2
Conflict of Interest Form

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT
Department of Veterans Affairs

INSTRUCTIONS: Complete this Statement to the best of your knowledge. Answering any question in the affirmative does not itself prevent you from conducting VA research or receiving VA funding. You will, however, need to provide additional information so that a determination can be made of how to best manage any conflict of interest that may be found.

Once you have completed the form, print a hardcopy, print your name at the top of each page, and initial and sign Section III.

IMPORTANT DEFINITIONS:
CLOSE RELATIVE – An individual who is related as father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half-brother, or half-sister.
DEPENDENT CHILD – A son, daughter, stepson, or stepdaughter and who either is (i) unmarried, under age 21, and living in your house, or (ii) considered dependent under the U.S. tax code.
ENTITY - Any person, for-profit or non-profit organization, institution, corporation, partnership, or governmental agency (other than a Federal agency).
OUTSIDE EMPLOYER – An entity with which you serve as officer, director, trustee or employee.

NAME (Last, First, Middle) _______

DUTY STATION _______

TELEPHONE AND FAX NUMBERS _______

AREA OF RESEARCH & STUDY TITLE _______

ROLE (check one) ☐ Principal Investigator ☐ Co-Principal Investigator ☐ Co-Investigator
☐ Study Chair* ☐ Site PI*
* Cooperative Studies Program only

SECTION I

1. INCOME AND COMPENSATION. Do you, your spouse, dependent Yes ☐ No ☐
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<tr>
<th>Question</th>
<th>Yes □</th>
<th>No □</th>
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<tr>
<td>2. BUSINESS RELATIONSHIPS.</td>
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<td>A. Current Relationships: Are you, your spouse, dependent child,</td>
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<td>general partner or other close relative serving as an officer, director,</td>
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<td>trustee, partner, or employee (paid or unpaid) with any entity whose</td>
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<td>financial interest could be affected by your area of research?</td>
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<td>B. Covered Relationships: Are you, your spouse, parent, dependent</td>
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<td>child, close relative, household member or general partner working or</td>
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<td>seeking to work (other than as an employee of the Federal Government)</td>
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<td>in your same area of research?</td>
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<td>C. Relationships in the Past Year: Have you, within the last year,</td>
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<td>served as an officer, director, trustee, general partner, agent, attorney,</td>
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<td>consultant, contractor or employee for any entity whose financial</td>
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<td>interest could be affected by your area of research?</td>
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<td>D. Business Arrangement or Agreements: Are you negotiating for, or</td>
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<td>do you have, any business arrangement or agreement, such as a future</td>
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<td>employment agreement, re-employment rights, consultant agreement,</td>
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<td>pending severance arrangement or retirement plan, with any entity</td>
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<td>whose financial interest could be affected by your area of research?</td>
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<td>3. PATENTS, COPYRIGHTS, LICENSES AND ROYALTIES. Are you, your spouse,</td>
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<td>dependent child, general partner, or outside employer:</td>
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<td>(i) listed as the inventor on a patent application;</td>
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<td>(ii) the owner of any patent or provisional patent;</td>
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<td>(iii) the holder of a copyright, or software or other intellectual</td>
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<td>property license;</td>
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<td>(iv) entitled to earn royalties now or in the future;</td>
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<td>(v) the author of training materials that are, or are going to be,</td>
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<td>commercialized;</td>
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<td>(vi) otherwise earning compensation from, or have a financial</td>
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<td>interest in, intellectual property (not covered elsewhere in this</td>
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<td>form) OR;</td>
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<td>(vii) have any other financial relationship not covered elsewhere in</td>
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<td>this form that could be affected by your area of research?</td>
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<td>4. NON-PUBLICLY TRADED COMPANIES. Do you, your spouse, dependent child</td>
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<td>or general partner have any stock, stock options, or other equity</td>
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<td>interest in a non-publicly traded company that does business in an</td>
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<td>area related to your research?</td>
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<td>5. SPECIFIC TYPES OF FINANCIAL INTERESTS.</td>
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<tr>
<td>A. Publicly-Traded Companies: Do you, your spouse or dependent</td>
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child (in the aggregate) own or have an equity interest (stock ownership, stock options, etc.) valued at more than $15,000 in a publicly-traded company or companies (aggregate value of all stocks in all such companies) that do business in an area related to your research?  

Note: This does not include stock controlled through a diversified mutual fund or a blind trust.

| B. Sector Mutual Funds: Do you, your spouse or dependent child (in the aggregate) have equity holdings valued at more than $50,000 in any sector mutual fund (or funds that concentrate in the same sector) whose holdings could be affected by your research?  
Note: A sector mutual fund concentrates its investments in an industry, business, single country other than the United States, or bonds of a single State within the United States. |
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<tr>
<td>Yes ☐</td>
<td>No ☒</td>
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</table>

- If you answered “yes” to any of the statements in Section I, you must fill out Section II.
- If you answered “no” to all statements in Section I, skip Section II, and proceed to Section III.

**SECTION II: SUPPLEMENTAL INFORMATION**

Please attach additional pages, if you need more space to fully respond.

1. **INCOME AND COMPENSATION.** If you answered yes in paragraph 1 of Section I, explain the source, value and reason for the income or other compensation.

2. **BUSINESS RELATIONSHIPS**  
A. Current or Future Relationships. If you answered yes in paragraph 2.A. of Section I, provide: (i) the name of the entity, (ii) the type of business, and (iii) how the entity could be affected by your area of research.
B. Covered Relationships. If you answered yes in paragraph 2.B. of Section I, identify: (i) the relationship between you and the person seeking to work in the same area of research, (ii) the actions the person is taking to work in the same area of research, and (iii) the capacity in which the person is seeking to work in the same area of research.

C. Relationships in Past Year. If you answered yes in paragraph 2.C. of Section I, provide: (i) name of the outside business, (ii) the type of business; (iii) your position with the outside business, and (iv) the date your relationship with the business ended.

D. Business Arrangement or Agreements. If you answered yes in paragraph 2.D. of Section I, provide: (i) name of entity with whom you have the agreement or arrangement, (ii) type of business conducted by entity, (iii) brief description of the arrangement or agreement with the entity, and (iv) description of the entity’s relation to your area of research.

3. PATENTS, COPYRIGHTS, LICENSES AND ROYALTIES. If you answered yes in paragraph 3 in Section I, identify: (i) what you, your spouse, dependent child, general partner or outside employer has, and (ii) how it could be affected by your area of research.
4. **NON-PUBLICLY TRADED COMPANIES.** If you answered yes in paragraph 4 of Section I, provide additional information below.

Name of Company: _____
Type of Equity Interest: _____
Describe the nature of the company and how it is related to your area of research.

5. **SPECIFIC TYPES OF FINANCIAL INTERESTS**
   A. Publicly Traded Companies. If you answered yes in paragraph 5.A. of Section I, provide additional information below.

   Name of Company: _____
   Type of Equity Interest: _____
   Value of Equity Interest: _____
   Describe the company’s business and how it is related to your area of research.

   B. Sector Mutual Funds. If you answered yes in paragraph 5.B. of Section I, identify the names of the relevant fund(s).

---

**SECTION III**

All Investigators must read, initial, and sign the acknowledgement below. Attach a summary describing your area of research and submit completed Statement to the R&D Committee or appropriate sub-committee.

**Acknowledgement**

By signing below, I certify that, to the best of my knowledge and belief, all of the information on this Statement is true, correct, and complete as of the date of my signature below.

I understand that false or fraudulent information on this Statement may be
grounds for not approving the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

I agree to update relevant information, contact my supervisor, and notify the R&D Committee or appropriate sub-committee with respect to any new financial interest(s) that requires me to change an answer on this form.

I understand that in addition to the disclosures required in this Statement, I am subject to the criminal conflict of interest statutes at Title 18 of the United States Code, Chapter 11, and the Executive Branch Standards of Conduct at Title 5 of the Code of Federal Regulations, Part 2635. Violation of these provisions may be sanctioned by civil and criminal penalties, as well as employment-related discipline such as removal or suspension.

(Signature)  (Date Signed)

---

**Declaration of No Changes to Financial Interests**

This declaration is to be used only if your financial interests have not changed since filing your last Statement. You must declare all of the following statements to be true. If you cannot do so, you must complete a new Statement.

After examining a copy of my last Research Financial Conflict of Interest Statement, I declare the following:

1. I have no new reportable income or compensation;
2. I have no new reportable relationships with any entity whose financial interest could be affected by my area of research;
3. I have no new patents, copyrights, licenses, or royalty payments that are related to my area of research;
4. I have no new reportable financial interests in any publicly or non-publicly traded company that does business in an area related to my research; and
5. I have no new reportable financial interests in any sector mutual fund that concentrates in an area related to my research.

I declare that the above statements are true, complete and correct, to the best of my knowledge.

(Signature)  (Date)

---

**PRIVACY ACT STATEMENT**

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by the VHA R&D Committee or appropriate sub-committee, and when necessary the VA Office of General Counsel, to determine compliance with applicable Federal conflict of interest laws and regulations and the impact of any real or perceived financial conflicts of interest on VA research. Additional disclosures of information in this report may be made:

1. to other VA research review committees and VA officials responsible for the approval or funding of research protocols;
2. if there is an indication of a violation or potential violation of law, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant
thereto, to the appropriate Federal, State or local agency charged with the responsibility of investigating or
prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued
pursuant thereto;

(3) to qualified reviewers for their opinion and evaluation of a proposal as part of the application review management
inspections; and

(4) to the Department of Justice (DOJ) upon official request in order for VA to respond to pleadings, interrogatories,
orders or inquiries from DOJ and to supply to DOJ the information to enable DOJ to represent the U.S. Government
in any phase of litigation or in any case or controversy involving VA.

Failure to file or report information or the falsification of required information may subject you to disciplinary action by the VA
or other appropriate authority. This may include limitation on or revocation of the privilege to conduct VA-approved research.
It may also be subject to criminal prosecution.
ACUP SOP Appendix 3
Animal Component of Research Protocol Form (ACORP)

Protocol #:
Protocol Title:
Principal Investigator:

Investigator Assurances

I agree to abide by the policies of the Louis Stokes Cleveland DVA Medical Center Institutional Animal Care and Use Committee (IACUC) and all applicable federal regulations.

I will adhere to the protocol as described and as modified.

I will submit any modifications of the protocol to the IACUC for review and approval before initiating them.

I will notify the IACUC of changes in the location of the animal research.

I will assist the IACUC in verifying compliance with the regulations.

I will notify the IACUC of any unexpected results that affect the welfare of the animals. I will report any unanticipated pain or distress, morbidity, or mortality to the attending veterinarian and the IACUC.

I understand and agree that emergency veterinary care, including euthanasia, will be administered to animals exhibiting unbearable pain distress or illness. Prior to any emergency treatment, the veterinary staff will make every effort to contact my representative or me.

I declare that all experiments involving live animals will be performed under my supervision or that of another qualified scientist. All other personnel involved in animal use in this project have been or will be trained in proper procedures relevant to this protocol, including but not limited to animal handling, administration of anesthetics and analgesics, aseptic technique, postoperative monitoring, and euthanasia. I will notify the IACUC when new employees are hired and will certify when their training to perform the relevant experimental procedures on live animals is complete.

I declare that the information provided in this protocol is accurate. If this project is to be funded, I certify that this protocol accurately describes all procedures in which I intend to involve laboratory animal subjects.

I declare that the studies described here do not unnecessarily duplicate previous work by others or by me.

______________________________  _________________________
Signature of Principal Investigator  Date
ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Version 3

Note: Use a separate form for each species. DO NOT include individual appendices if they are not relevant to the protocol being described. To check boxes, right click, choose properties, then click to check the box. Define all abbreviations the first time they are used. To add a row to a table, click inside one of the existing table cells, then select Table, Insert, Rows from the main menu of the program.

A. ACORP 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 ACORP (only one):
5. Funding Source. Indicate the source(s) of funds that will be used to perform these animal procedures once approved by the VA IACUC:
   - Department of Veterans Affairs
   - 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 ACORP for a new project?
   - Yes. Proceed to item 7.
   - No. Answer A.6.a-d. below.
   a. Indicate the status of this ACORP below:
      - This is an unchanged, approved ACORP intended for a new funding source.
      - This is a revised ACORP with a new funding source.
      - This is a revised ACORP that reflects changes or additional, new studies.
      - This ACORP is submitted as a three-year (3-year) renewal (see item d. below).
      - Other. Please specify:
   b. Previous ACORP title:
   c. Previous IACUC approval number (VA and affiliate, if applicable):
   d. If this is a three-year renewal, provide a progress report describing work accomplished during the last approval period. Include the number of animals used, the objectives that were met and how the work proposed in this renewal extends the previous studies. If not applicable, go to item 7.
7. Do you plan on performing the animal procedures described in this form even if you do not receive intramural VA or 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:

Proposal Overview

B. Lay Description. Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project might improve the health of people and/or other animals. A scientific abstract from a grant proposal is not acceptable. Once completed, proceed to item C.

C. Experimental Design.

1. Using non-technical (lay) language that a senior high school student would understand, describe the experimental design in no more than one or two paragraphs.

2. In language scientific colleagues outside of your discipline would understand, describe the experimental design for the animal experiments planned, and the sequence of events to reveal what happens to the animals. Include all procedures and manipulations, and explain why they must be performed. Give your best estimate of how many animals will undergo the procedures or manipulations described. For complicated experimental designs, a flow chart, diagram, or table is strongly recommended to help the IACUC understand what is proposed. Do not describe the details of surgical procedures, monoclonal antibody production, or behavioral training here. Such details are requested later in appendices. Once completed, proceed to item D.

D. Describe the characteristics of the selected species, strain, stock, mutant, or breed that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, availability, data from previous studies, and unique anatomic or physiologic features. Once completed, proceed to item E.

Personnel

E. 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. (Qualifications to perform euthanasia will be requested in item U.3. and need not be given here.) Once completed, proceed to item F.
F. 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 G.

G. Occupational Safety and Health.

1. Have all personnel listed in item E. been enrolled in the Occupational Health and Safety Program for those with laboratory animal contact?
   - Yes. Proceed to item G.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 G.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, then proceed to item H:
   - No. Proceed to item H.

H. Complete the following table; then proceed to item I.

<table>
<thead>
<tr>
<th>Strain, Stock, Mutant, or Breed</th>
<th>Gender</th>
<th>Age/Size</th>
<th>Source (Vendor)</th>
<th>Health Status*</th>
</tr>
</thead>
</table>

*For each strain, stock, mutant, or breed listed, provide information about the expected status of the animals:
- For rodents and rabbits, indicate specific-pathogen-free (SPF), gnotobiotic (germ-free or defined flora), conventional, feral, or other description.
- For dogs, cats, pigs, and other “large animals”, indicate specific-pathogen-free (SPF), conditioned, conventional, feral, or other description.
- For non-human primates, indicate viral status (e.g., herpes B, SIV, etc.)
- Also indicate here if animals will be surgically altered by the vendor (e.g., ovariectomized rats).

I. 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. You are required by VA policy to describe planned procedures for the fourth and fifth years of a submitted VA grant even though, under PHS policy, the IACUC must perform a new review three years after the initial approval date. Once completed, proceed to item J.
**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.)

<table>
<thead>
<tr>
<th>Breed/Strain/Mutant</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
</table>

**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.

<table>
<thead>
<tr>
<th>Breed/Strain/Mutant</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
</table>

**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.

<table>
<thead>
<tr>
<th>Breed/Strain/Mutant</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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</table>

**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. LD50, mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.

<table>
<thead>
<tr>
<th>Breed/Strain/Mutant</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
</table>

**TOTALS:** Bring all totals for each year down, by breed/strain/mutant.

<table>
<thead>
<tr>
<th>Breed/Strain/Mutant</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
</table>

**J. Description of USDA Category D and E procedures.** Are any USDA Category D or E studies planned?

- [ ] No. Proceed to item K.
- [x] Yes. Complete items J.1. and J.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 J.2. **For any surgical procedures you will**
describe in Appendix 5, enter only a brief description in the “Procedure” column, then enter “See Appendix 5 for details.”

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency of monitoring after the procedure and how long animals will be monitored</th>
<th>Person(s) doing the monitoring</th>
<th>Analgesic, sedative, or anesthetic used, plus dose, route, and duration</th>
</tr>
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</table>

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. If the species is covered by USDA regulations, 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 J.1. above.

K. **Justification for number of animals requested and group sizes.** Describe how the estimated number of animals needed for the experiments was determined. When appropriate, provide the number and type of experimental and control groups in each experiment, the number of experiments planned, and the number of animals in each group. The ILAR **Guide** states that whenever possible, the number of animals requested should be justified statistically. A power analysis is strongly encouraged to justify group sizes when appropriate. Once completed, proceed to item L.

L. **Laboratory Animal Veterinary Support.** Complete items L.1-L.3, then proceed to item M.

1. Give the name of the laboratory animal veterinarian responsible for providing adequate care to the animals that will be used and 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 ACORP and provide comments to the PI so that the ACORP 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):
M. **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 item M.2:
   - [ ] Gnotobiotic (germ-free and defined flora) isolators
   - [ ] 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 rodent shoebox caging with no filter 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 M.3.
   - [ ] No. Proceed to item M.4.
   - [ ] Not Applicable; the species involved is not a social animal. Proceed to item M.4.

3. Please provide a justification for housing social animals singly; then proceed to item M.4.

4. The ILAR *Guide for the Care and Use of Laboratory Animals* recommends the use of contact bedding (i.e., shoebox or microisolator cages) instead of wire mesh floors for housing rodents. Will rodents be housed on suspended wire mesh floors or other flooring in which the animals do not rest on bedding?
   - [ ] Not applicable; this ACORP does not describe rodent use. Proceed to item M.6.
   - [ ] No. All rodents will be housed in shoebox or other caging in which the animals rest directly on bedding. Proceed to item M.6.
   - [ ] Yes. Proceed to item M.5.

5. Why is caging with wire mesh flooring necessary?

6. Indicate the appropriate response below:
   - [ ] This ACORP does not address the use of dogs, primates, or genetically engineered or modified (e.g. transgenic/knockout/knockin) animals. Proceed to item M.7.
   - [ ] This ACORP addresses the use of dogs. Answer item M.6.a. below, and M.6.c if applicable.
   - [ ] This ACORP addresses the use of primates. Answer item M.6.b. below, and item M.6.c. if applicable.
   - [ ] This ACORP addresses the use of genetically engineered or modified animals. Answer item M.6.c. below.

   a. Is there any scientific justification for excluding the dogs in this study from the institutional dog exercise plan required by USDA?
      - [ ] No. Proceed to item M.7.
      - [ ] Yes. Provide a scientific justification for excluding the dogs; then proceed to item M.7:

   b. Is there any scientific justification for excluding the primates from the institutional primate psychological enrichment plan required by USDA?
      - [ ] No. Proceed to item M.7.
      - [ ] Yes. Provide a scientific justification for excluding the primates; then proceed to item M.7:
c. Do the genetically engineered or modified animals exhibit any characteristic clinical signs or abnormal behavior related to their genotype?
   □ No. Proceed to item M.7.
   □ Yes. Describe here, then proceed to item M.7.

7. 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 N.
   □ Yes. Explain what implantation and wound management measures will be taken to minimize the chances of chronic infections around the device(s) where they penetrate the skin (then proceed to item N):

N. Housing Sites.

1. Will all animals purchased with VA or VA Foundation funds be housed only in VA facilities?
   □ Yes. Proceed to item N.2.
   □ No. Complete and attach ACORP Appendix 1, “Use Of a Non-VA Facility to House Animals Purchased with VA or VA Research And Education Corporation Funds”, then go to item N.2.

2. Give the location(s), inside or outside of the animal facility, where animals will be housed permanently or temporarily, then proceed to item O:

O. Antibody Production. Will animals be used to produce monoclonal or polyclonal antibodies, or will existing hybridoma cell lines be injected into animals to harvest antibody?
   □ No. Proceed to item P.
   □ Yes. Complete and attach Appendix 2, “Antibody Production;” then proceed to item P.

P. 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. (Note: The following substances do not need to be entered in Appendix 3 unless they are hazardous: routine pre- or post-operative drugs described in the Surgery Appendix [Appendix 5], antigens, adjuvants, hybridomas described in the Antibody Production Appendix [Appendix 2], and euthanasia agents entered in item U, Euthanasia.)
   □ No. Proceed to item Q.
   □ Yes. Complete and attach Appendix 3, “Test Substances;” then proceed to item Q.

Q. Location of procedures. Complete the table below, indicating where all non-surgical procedures and manipulations will be performed. The IACUC must be aware of all procedures performed outside of the animal facility. To help the IACUC track the sites of animal use outside the animal facility, give the location of any laboratory or other areas outside of the animal facility in which animals will be manipulated in any way. Be sure to include the sites of procedures such as radiography, fluoroscopy, computed axial tomography (CT), or magnetic resonance imaging (MRI) that may be performed outside the animal facility.

<table>
<thead>
<tr>
<th>Non-surgical Procedure</th>
<th>Building and Room Number</th>
<th>Method of discreet transport, if required through non-research areas (enter N/A if not applicable)*</th>
</tr>
</thead>
</table>
*Describe how animals will be transported to and from these sites. Transportation must be in accordance with the Guide, USDA regulations, and PHS policy in climate-controlled vehicles and sanitizable transport cages when appropriate. Such transport must be discreet such that hospital staff and patients are not aware of the transport, and are not exposed to allergens and/or body fluids from the transported animal(s). Once completed, proceed to item R.*

**R. Body Fluid, Tissue, and Device Collection.**

1. Will any body fluids, tissues, or devices be collected from animals **AFTER** euthanasia?
   - No. Proceed to item R.2.
   - Yes. List the fluids, tissues, and/or devices here; then proceed to item R.2.:

2. Will any body fluids, tissues, or implanted devices or materials be collected from animals **BEFORE** euthanasia?
   - No. Proceed to item S.
   - Yes. Proceed to item R.3.

3. Is collection in live animals limited to blood collection associated with antibody production?
   - No. Complete and attach Appendix 4, “Antemortem Specimen Collection.” Then proceed to item S. If the body fluid, tissues, or devices are collected as a surgical procedure, please be sure to also describe these collections as part of the surgical protocol in Appendix 5, “Surgery.”
   - Yes. Because blood collection associated with antibody collection is already described in Appendix 2, “Antibody Production”, DO NOT complete Appendix 4, “Antemortem Specimen Collection.” Proceed to item S.

**S. Surgery.** Will survival or non-survival surgery be performed?

- No. Proceed to item T.
- Yes. Complete and attach Appendix 5, “Surgery;” then proceed to item T.

**T. 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 U.:  

**U. Euthanasia.** Will animals be euthanatized as part of the planned studies?

- No. Describe the final disposition of the animals here, then proceed to item U.4:
- Yes. Complete items U.1. - U.4. below; then proceed to item V.

1. Describe the exact method of euthanasia for each animal used. Include the agents used, dose (as applicable), and route of administration:

2. Are all euthanasia methods acceptable according to the latest report of the AVMA Panel on Euthanasia? (if you are unsure how to answer, contact your veterinarian or IACUC for guidance)
   - Yes. Proceed to item U.3.
No. Justify any method that is not considered “acceptable” by the latest report of the AVMA Panel on Euthanasia, then proceed to item U.3:

3. List the personnel who will perform euthanasia and indicate their training and experience with the method of euthanasia and the species involved. If personnel are not yet trained, indicate so and explain how they will be trained before performing euthanasia themselves.

4. If the animal care staff find an animal dead, how should the carcass be handled (e.g. refrigerated or frozen), and should a member of your staff be contacted immediately?

V. 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 ACORP? 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 W.
☐ No. Proceed to item W.

W. Consideration of Alternatives and the Prevention of Unnecessary Duplication. Complete items W.1 through W.5 below; then proceed to item X. 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 W.2 through W.5 below. You must provide complete information in the first four columns of the table to comply with USDA Policy #12.

<table>
<thead>
<tr>
<th>Name of the database(s)</th>
<th>Date search was performed</th>
<th>Period (years) covered by each search</th>
<th>Key words and/or search strategy used</th>
<th>Indicate below for which alternative mandate each search was conducted by placing an “X” in the proper column</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>Computer models or in vitro techniques (item W.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of less-sentient species (item W.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of less stressful model or methods, or fewer animals (item W.4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lack of unnecessary duplication (item W.5)</td>
</tr>
</tbody>
</table>

2. Could any of the animal procedures described in this ACORP 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. 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:

X. Other Regulatory Considerations. Complete items X.1, X.2, and X.3 below; then proceed to item Y.

1. Controlled drugs.

   a. Will all drugs used in animals and classified as controlled substances by the DEA be stored in a double-locked cabinet, and be accessible only to authorized personnel in accordance with VA policy?
      - Not applicable- no controlled drugs will be used. Proceed to item X.2.
      - No. Please explain here, then go to item X.1.b.:
      - Yes. Complete item X.1.b.

   b. List the controlled substances that will be used in animals for this project here, and include the building and room number where they will be stored, then go to item X.1.c.:

   c. To comply with VA pharmacy policies, all controlled substances used on VA property must be ordered through and received by the local VA pharmacy prior to issue for research use. Will the use of all controlled substances comply with these VA pharmacy policies?
      - No. Please explain (then proceed to item X.2):
      - Yes. Proceed to item X.2.

2. Will any human patient procedural areas be used for these animal studies?
   - No. Proceed to item X.3.
   - Yes. Complete and attach Appendix 7, “Request to Use Patient Procedural Area;” then proceed to item X.3.

3. Will an explosive anesthetic or other explosive agent be used in any portion of these animal studies?
   - No. Proceed to item Y.
   - Yes. Complete and attach Appendix 8, “Request to Use Explosive Agent;” then proceed to item Y.

Y. Appendices. Please indicate which of the following Appendices are completed and attached. Do not attach blank appendices which are not applicable to this ACORP. Check with your IACUC to see if an optional Appendix 9, “Additional Local Information”, is required.

- Appendix 1, “Use of a Non-VA Facility to House Animals Purchased with VA or VA Research and Education Corporation Funds” (ref item N)
- Appendix 2, “Antibody Production” (ref item O)
Z. **Certifications.** **Important:** If this ACORP will be submitted to VA Central Office for Just-In-Time approval prior to receiving VA funding, the signatures of the Principal Investigator(s), IACUC Chair and veterinarian must appear below in items Z.1 and Z.3. The requirement for an R&D Committee Chair signature and the requirement that signatures be less then a year old have been dropped.

1. **Certification by Principal Investigator(s).**

To the best of my knowledge, I certify that the information provided in this Animal Component of Research Protocol (ACORP) 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 ACORP 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 ACORP;
- 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 an institutional Occupational Health and Safety Program prior to their contact with animals, or have declined in writing to participate, if allowed by local policy;
- I will provide my after-hours telephone numbers to the animal care staff in case of emergency.

<table>
<thead>
<tr>
<th>Name of Principal Investigator(s)</th>
<th>Signature</th>
<th>Date</th>
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2. **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.** To the best of their abilities, the undersigned verify that the IACUC has evaluated the care and use of the animals described in 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, and find the use of animals described in this ACORP to be appropriate.

<table>
<thead>
<tr>
<th>Name of Attending Veterinarian (VMO or VMC)</th>
<th>Signature</th>
<th>Date</th>
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<tr>
<td>Name of IACUC Chair</td>
<td>Signature</td>
<td>Date</td>
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### ACORP Appendix 1

**USE OF A NON-VA FACILITY TO HOUSE ANIMALS PURCHASED WITH VA OR VA RESEARCH AND EDUCATION CORPORATION FUNDS**

**Version 3**

1. Indicate which non-VA facilities will house animals purchased with VA or VA Research and Education Corporation funds for this project, and give the current AAALAC International accreditation status for each. Be sure to consider affiliated institutions and contract facilities that purchase and house animals on your behalf to make custom antibodies or other biological products. Consult with your veterinarian or IACUC to determine which institutions must be entered. USDA policies and PHS policy clarifications may also be helpful. Once completed, proceed to item 2.

<table>
<thead>
<tr>
<th>Non-VA Facility Name</th>
<th>Is this facility accredited by AAALAC?</th>
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<tbody>
<tr>
<td></td>
<td>Yes</td>
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*According to VHA Handbook 1200.7, “Use of Animals in Research”, paragraph 7.f., all VA animal facilities and affiliate or other animal facilities that house animals purchased with VA (including VA Research and Education Corporation) funds must be accredited by AAALAC. Under exceptional circumstances, a waiver may be requested in writing from the CRADO (Chief Research and Development Officer) or designee through the CVMO (Chief Veterinary Medical Officer). See Appendix A of VHA Handbook 1200.7 for information on how to contact the CVMO.

2. In what non-VA building(s) and room(s) will the animals be housed?
3. Return to item N.2. on the ACORP.

ACORP Appendix 2
ANTIBODY PRODUCTION
VERSION 3

1. Monoclonal Antibody Production. Will monoclonal antibodies be produced in animals or harvested from hybridoma cell lines as part of this project?
   - No. Proceed to item 3.
   - Yes. Complete item 1.a.

   a. Is antibody harvest limited to existing hybridoma cell lines with no further immunizations or lymphocyte fusions planned?
      - Yes. Proceed to item 2 below.
      - No. Fill out items 1.b and 1.c below; then proceed to item 2.

   b. Complete the following table regarding the immunization protocol for the animals prior to lymphocyte harvest for hybridoma creation. For each antigen for which multiple immunization days will be used, use a separate row in the table for each immunization day.

<table>
<thead>
<tr>
<th>Injection day (e.g. day 0, 7, 30, etc.)</th>
<th>Antigen</th>
<th>Total amount (mg) and volume (ml) of antigen injected</th>
<th>Identity and volume (ml) of adjuvant injected</th>
<th>Total injection volume per animal (antigen plus adjuvant; ml)</th>
<th>Divided into how many injections?</th>
<th>Injection route and location of injections on body</th>
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</table>

   c. If feeder cells for supporting hybridoma colony growth will be collected from animals, describe the exact procedures that will be used to collect the feeder cells and the number of animals needed for this purpose:

2. You must consider alternate research methods that can replace the use of animals. Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?
   - No. Proceed to item 2.d.
   - Yes. Complete items 2.a-2.c below; then proceed to item 2.d.

   a. Explain why *in vitro* cell culture systems for harvesting monoclonal antibodies are not adequate to meet the research objectives:

   b. Complete the following table:
c. What criteria will be used to determine if animals should be euthanatized prior to the last planned abdominal tap?

d. **Blood collection.** Will survival blood collections be obtained from animals following immunization or as a “pre-bleed” prior to immunization?

- [ ] No. Proceed to item 3.
- [ ] Yes. Complete items 1) and 2) below; then proceed to item 3.

1) Complete the following table; include any “pre-bleeds” prior to immunizations:

<table>
<thead>
<tr>
<th>Site of blood collection</th>
<th>Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)</th>
<th>Number of blood collections</th>
<th>Interval between collections</th>
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</table>

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

- [ ] No. **Justify the omission of pain-relieving agents** here; then proceed to item 3:

- [ ] Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration here; then proceed to item 3:

3. **Polyclonal Antibody Production.** Will polyclonal antibodies be produced in this species of animal as a part of this project?

- [ ] No. **Do not** complete items 3.a.-3.c. Go to item 4 below.
- [ ] Yes. Complete items 3.a.-3.c., then go to item 4.

a. Complete the following table. For each antigen for which multiple immunization days will be used, use a separate row in the table for each day:
b. List possible adverse effects in animals that might be seen from the proposed antigen or adjuvant injections and what measures will be taken should these adverse effects occur:

c. **Blood collection.** Will survival blood collections be obtained from animals following immunization or as a “pre-bleed” prior to immunization?

  - [ ] No. Proceed to item 4.
  - [ ] Yes. Complete items 1) and 2) below; then proceed to item 4.

1) Complete the following table; include any “pre-bleeds” prior to immunizations:

<table>
<thead>
<tr>
<th>Site of blood collection</th>
<th>Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)</th>
<th>Number of blood collections</th>
<th>Interval between collections</th>
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</table>

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

  - [ ] No. Justify the omission of pain-relieving agents here; then proceed to item 4:
  - [ ] Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration here; then proceed to item 4:

4. **Terminal blood collection.** Will animals used for antibody production be exsanguinated as a method of euthanasia?

  - [ ] No. Go to item 5.
  - [ ] Yes. Complete items 4.a, b., and c. below, then go to item 5.

  a. Describe the method of exsanguinations:

  b. Will anesthetics, tranquilizers, or analgesics be used prior to exsanguination?

    - [ ] No. Justify the omission of pain-relieving agents here; then proceed to item 5:
Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration here; then proceed to item 5:

c. How will you make sure that the animals are dead following blood withdrawal?

5. How will the antigens or cell lines listed in items 1.b., 2.b., and 3.a. be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people after injection?

6. Return to the main ACORP form and continue with item P.

ACORP Appendix 3
TEST SUBSTANCES
Version 3

1. Toxic Agents. Will toxic chemicals, toxic pharmacologic agents, known or suspected mutagens, carcinogens, teratogens, DNA-binding, or other similar agents be used in animals?

☐ No. Proceed to item 2.
☐ Yes. Complete items 1.a, 1.b, 1.c, and 1.d, then proceed to item 2.

a. Table of toxic agents:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Diluent</th>
<th>Route of admin.</th>
<th>Dose (e.g. mg/kg) and Volume (ml)</th>
<th>Frequency and duration of administration</th>
<th>Reason for admin., and expected effects</th>
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b. Indicate which of the above agents, if any, are known or suspected mutagens, carcinogens, or teratogens:

c. Are any of the agents above on the CDC/USDA list of “select agents” that might have bioterrorism? Check the appropriate response below and proceed to item 1.d.

☐ No.
☐ Yes, but agent(s) will be used in quantities that fall below minimums specified by "select agent" legislation, and thus these agents are not covered by "select agent" legislation.
☐ Yes. Ask your research office to contact the VACO Chief Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC and/or USDA license and VACO approval before beginning your studies with this agent.

d. Will the animals be anesthetized or sedated when these agents are administered?

☐ No. Proceed to item 2.
☐ Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2:
2. **Infectious Agents.** Will bacteria (including rickettsia), viruses, fungi, protozoa, prions, or other infectious agents be used in animals? If the agent will have a radioactive label added, also complete item 4 below. Likewise, if the infectious agent contains recombinant nucleic acid, fill out item 6 below for the agent as well.

- [ ] No. Proceed to item 3.
- [ ] Yes. Complete items 2.a, 2.b, 2.c, and 2.d; then proceed to item 3.

a. Complete the table below:

<table>
<thead>
<tr>
<th>Agent and strain or construct</th>
<th>CDC Biosafety Level of agent (BSL1, 2, 3, 4)</th>
<th>Route of admin.</th>
<th>Dose (e.g. CFU, PFU) and volume administered (ml)</th>
<th>Frequency of administration</th>
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b. Has an antibiogram, anti-viral drug sensitivity screen, or other appropriate drug sensitivity panel been determined for the agent(s) listed to assist physicians in selecting proper therapy if an inadvertent human infection occurs?

c. Will the animals be anesthetized or sedated when these agents are administered?

- [ ] No. Proceed to item 2.d.
- [ ] Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.d:

d. Are any of the agents on the CDC/USDA list of “select agents” that might have bioterrorism uses? Check the appropriate response below and proceed to item 3.

- [ ] No.
- [ ] Yes. Ask your research office to contact the VACO Chief Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC and/or USDA license and VACO approval before beginning your studies with this agent.

3. **Biological Materials.** Will serum, cell lines, tissue, nucleic acid or other biological materials be administered to animals? If any of the agents are radioactive or will have a radioactive label added, also complete item 4 for that agent.

- [ ] No. Proceed to item 4.
- [ ] Yes. Complete items 3.a., 3.b., and 3.c.; then proceed to item 4.

a. Table of biological materials:

<table>
<thead>
<tr>
<th>Material (e.g. fluid, cells, tissues)</th>
<th>Diluent</th>
<th>Source (e.g. vendor, other animals, colleague)</th>
<th>Route of admin.</th>
<th>Dose (e.g. ml/kg, mg/kg, cells/kg) and volume (ml)</th>
<th>Freq. and duration of admin.</th>
<th>Reason for admin., and expected effects</th>
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</table>
b. Will the animals be anesthetized or sedated when these agents are administered?
   - No. Proceed to item 4.
   - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 4:

c. How will these materials be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people?

4. Radioactive Agents. Will radioactive compounds or agents be administered to animals?
   - No. Proceed to item 5.
   - Yes. Complete items 4.a., 4.b., and 4.c.; then proceed to item 5.

a. Table of radioactive agents:

<table>
<thead>
<tr>
<th>Radioactive Agent (include isotope)</th>
<th>Diluent</th>
<th>Agent dose (mg/kg) and Vol. (ml)</th>
<th>Activity (e.g. mCi/kg)</th>
<th>Route of admin.</th>
<th>Frequency and duration of admin.</th>
<th>Reason for admin., and expected effects</th>
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b. Which investigator has been given permission by the Radiation Safety Committee or equivalent committee to utilize the isotope(s) indicated above?

c. Will the animals be anesthetized or sedated when these agents are administered?
   - No. Proceed to item 5.
   - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 5:

5. Other Agents. Will other substances not listed previously in this appendix be administered to animals? Do not include anesthetics/analgesics/sedatives you will describe elsewhere in the ACORP as part of surgery and postoperative care.
   - No. Proceed to item 6.
   - Yes. Complete items 5.a. and 5.b.; then proceed to item 6.

a. Table of other agents:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Diluent</th>
<th>Agent dose (e.g. mg/kg) and Vol. (ml)</th>
<th>Route of admin.</th>
<th>Frequency and duration of admin.</th>
<th>Reason for admin., and expected effects</th>
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b. Will the animals be anesthetized or sedated when these agents are administered?
   - No. Proceed to item 6.
Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 6:

6. **Recombinant nucleic acid and recombinant infectious agents.**
   a. Do any of the agents noted above in items 1-5 above have recombinant nucleic acid in them?
      - No. Proceed to item 7.
      - Yes. Answer item 6.b.
   b. Are the recombinant constructs exempt from the animal research guidelines included in the latest version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* publication?
      - No. You must conduct the animal experiments involving recombinant nucleic acid according to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Consult with your Biosafety Committee and veterinarian to make sure you comply. Go to item 7.
      - Yes. Go to item 7.

7. **Pain or Distress.** Will animals potentially experience pain and/or distress as a result of the administration of agents listed above in items 1, 2, 3, 4, 5, or 6?
   - No. Proceed to item 8.
   - Yes. Describe the nature of the pain and/or distress that animals might experience and describe measures that will be taken to alleviate any pain and/or distress here, then proceed to item 8:

8. **Hazardous/Toxic Agents.** Are any of the agents listed above in items 1-6 hazardous or toxic to humans or animals, or covered by the *NIH Guidelines for Recombinant DNA and Gene Transfer*?
   - No. You have completed this appendix; no further information is required in this appendix. Go to item Q on the ACORP. YOU DO NOT NEED TO GET SIGNATURES IN ITEM 9. BELOW!
   - Yes. Complete items 8.a., 8.b., and 9; then return to item Q on the ACORP.
   a. Table of hazardous agents, committee approvals, and personnel exposed:

<table>
<thead>
<tr>
<th>Toxic or hazardous agent(s) from items 1-5 above, or non-exempt agent(s) from item 6.</th>
<th>Safety, biosafety, or radiation safety committee that has approved the use of this hazardous agent</th>
<th>Indicate whether VA or affiliate committee</th>
<th>List all animal facility staff who will come in contact with animals given these agents or with contaminated bedding, cages, or other items.</th>
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   b. Detail how the individuals listed in the table above (item 8.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:

9. **Signatures.** By our signatures, we certify that:
a. Before any animal experiments involving the agents listed in item 8.a. are performed, SOPs designed to protect all animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and the IACUC; and 
b. All staff that might be exposed to these agents will be informed of possible risks and will be properly trained to follow the SOPs to minimize the risk of exposure. As is appropriate, concurrence signatures from biosafety or radiation safety personnel are also required as shown.

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<th>Principal Investigator(s)</th>
<th>Signature(s)</th>
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<th>Institutional Veterinarian</th>
<th>Signature</th>
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<th>Biosafety Officer or Chair, Research Safety or Biosafety Committee (typed)</th>
<th>Signature</th>
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<thead>
<tr>
<th>Radiation Safety Officer, or Chair, Radiation Safety or Isotope Committee (typed)</th>
<th>Signature</th>
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<th>IACUC Chair (typed)</th>
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### ACORP Appendix 4
### ANTEMORTEM SPECIMEN COLLECTION
### VERSION 3

1. **Blood Collection.** Will blood be collected from live animals (anesthetized or awake) as a part of this proposal?
   - [ ] No. Proceed to item 3.
   - [ ] Yes, but all collections are described in Appendix 2, “Antibody Production”, so no further information need be provided here; proceed to item 3.
   - [ ] Yes. Complete the table below; then proceed to item 2.

<table>
<thead>
<tr>
<th>Site and Method of blood collection</th>
<th>Amount of blood collected, expressed as volume (ml) and % of body weight (assume 1 ml of blood weighs 1 gram)</th>
<th>Number of blood collections</th>
<th>Interval between collections</th>
</tr>
</thead>
</table>
2. **Use of Anesthetics, Tranquilizers, or Analgesics for Blood Collection.** Will anesthetics, tranquilizers, or analgesics be used to prevent pain or stress during collection of blood described in item 1 above?

- □ No. Justify the omission of pain-relieving agents (either scientifically or because the collection method involves no or momentary pain) and completely describe the physical restraint that will be used during collection here:

- □ Yes. Complete the following table, then proceed to item 3.

<table>
<thead>
<tr>
<th>Anesthetic, tranquilizer, or analgesic agent</th>
<th>Dose (mg/kg) &amp; volume (ml)</th>
<th>Route</th>
<th>Frequency</th>
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3. **Other Tissue Collection.** Will other body fluids (e.g. cerebrospinal fluid, peritoneal fluid, urine) or tissues be collected from live animals (awake or anesthetized) as a part of this protocol?

- □ No. Proceed to item 5.

- □ Yes. Complete the following table; then proceed to item 4.

<table>
<thead>
<tr>
<th>Tissue or fluid collected</th>
<th>Site &amp; method of collection</th>
<th>Amount (g) or volume (ml)</th>
<th>Number of collections</th>
<th>Interval between collections</th>
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4. **Use of Anesthetics, Tranquilizers, or Analgesics for Collection of Fluids or Tissues.** Will anesthetics, tranquilizers, or analgesics be used to prevent pain or stress during collection of body fluids or tissues described in item 3 above?

- □ No. Justify the omission of pain-relieving agents (either scientifically or because the collection method involves no or momentary pain) and completely describe the physical restraint that will be used during collection here, then go to item 5:

- □ Yes. Complete the following table, then go to item 5.

<table>
<thead>
<tr>
<th>Anesthetic, tranquilizer, or analgesic agent</th>
<th>Dose (mg/kg) &amp; volume (ml)</th>
<th>Route</th>
<th>Frequency</th>
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5. Proceed to item S on the ACORP.
ACROP Appendix 5  
SURGERY  
VERSION 3.1

1. **Surgery Classification.** The *Guide* defines a major survival surgery as a surgery in which a major body cavity is penetrated and exposed or surgery in which substantial impairment of physical or physiological functions is produced. Examples of such surgeries provided in the *Guide* include laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation.

   a. Will major survival surgery be performed on any animal as part of the proposed experimental plan?
      - [ ] No. Proceed to item 2.
      - [ ] Yes. Proceed to item 1.b. below.

   b. Will more than one major survival surgery be performed on any animal as part of the proposed experimental plan?
      - [ ] No. Proceed to item 2.
      - [ ] Yes. Complete item 1.c. and 1.d. below.

   c. Provide a **complete scientific justification** for performing more than one major survival surgery on individual animals:

   d. Give the interval(s) between the multiple surgeries, and the rationale for choosing the interval(s) here, then proceed to item 2:

2. **Description of Procedure(s).** Describe the surgical procedure(s) in enough detail so that the IACUC reviewers can determine what procedure(s) are actually being performed. If several different surgeries are being performed, be sure to describe each one. When finished, proceed to item 3:

3. Provide the names of the personnel who will perform the surgery; then proceed to item 4. Note that the surgical experience of each person involved in surgery should be listed in item E of the ACROP:

4. Provide the names of the personnel who will perform the anesthetic induction and monitor the animal during surgery here, then proceed to item 5:

5. Provide the building and room number(s) where the surgical procedure(s) will be performed. A dedicated surgical facility must be used for major survival surgeries on non-rodent species (the definition of a major survival surgery is provided in item 1 above). If allowed by local policy, non-survival surgery on non-rodent species and survival surgery on rodent species may be performed in a procedure room or laboratory. Then proceed to item 6:

6. **Pre-operative procedures.** Pre-operative procedures should include all preparations of the animal(s) for surgery. Check and describe which of the following procedures will be performed. Then proceed to item 7.
   - [ ] Fasting (rarely used in rodents or rabbits). **Indicate the length of the fasting period:**
   - [ ] Withhold water. **Indicate the length of time that water will be withheld:**
Catheter placement. Indicate the site(s) in which venous catheter(s) will be placed for vascular access during surgery:

☐ Other. Describe other pre-operative procedures:

7. **Pre-operative medications.** Complete the following table. Include any antibiotics, sedatives, or tranquilizers, and the anesthetic agent(s) that will be used to induce anesthesia prior to surgical site preparation; then proceed to item 8.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (mg/kg) &amp; volume (ml)</th>
<th>Route</th>
<th>Frequency (e.g. times/day)</th>
<th>Duration (e.g. days)</th>
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8. **Preparation of the surgical site.** Detail how the surgical site(s) will be prepared prior to surgery. Include details of hair-clipping, skin disinfection, and the use of surgical drapes. Then proceed to item 9:

9. **Intraoperative medications.** Complete the following table including any anesthetic agents, paralyzing agents, fluids, or other pharmaceuticals that will be administered to the animal during surgery. Also include experimental pharmaceuticals. Then proceed to item 10.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (mg/kg) &amp; volume (ml)</th>
<th>Route</th>
<th>Frequency</th>
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10. **Paralyzing agents.** Are any of the above medications considered paralyzing agents?

☐ No. Proceed to item 11.

☐ Yes. **Very Important!!** Federal regulations prohibit the use of paralytics (neuromuscular blocking agents) for surgery unless other appropriate anesthetic agents are used to induce a surgical plane of anesthesia. Paralytics do not provide any pain relief; therefore, animals are unable to respond physically to pain because motor reflexes are paralyzed. Justify the use of these agents and indicate how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain. Then proceed to item 11:

11. **Physical support.** Describe any physical methods used to support patients during surgery (e.g. heating pads, blankets, etc.); then proceed to item 12:

12. **Intra-operative monitoring.** Describe methods used to monitor the state of anesthesia and general well-being of the animal during surgery. Then proceed to item 13:

13. Will the animals regain consciousness following surgery?

☐ No. You have completed this appendix. **No further information is required in this appendix. Return to item T on the ACROP itself.**
Yes. Proceed to item 14.

14. **Survival surgery considerations and post-operative care.** Complete items 14.a-f. below. Then proceed to item 15.

   a. How long will the animal(s) survive after surgery? (If multiple surgeries are planned, answer for the last surgery before euthanasia):

   b. Is the room where the procedures will be performed (listed in item 5 above) suitable for sterile/aseptic surgery?

   c. Indicate which of the following procedures will be used to maintain a sterile field during surgery:

   - Sterile instruments.
   - Surgeon cap.
   - Sterile gloves.
   - Surgeon scrub.
   - Sterile drapes.
   - Sterile gown.
   - Face mask.
   - Other. Describe:

   d. List any methods used to support the patients in the immediate post-operative period (e.g., heating pads, blankets, fluids, etc.):

   e. Unless scientifically or otherwise justified to the IACUC’s satisfaction, you are obligated to routinely provide post-operative pain relief for all vertebrate animals undergoing survival surgery. Do you plan to use analgesics to provide postoperative pain relief to the animals following surgery?

   - No. Provide a justification for not using postoperative analgesics here:

   - Yes. Complete the following table listing post-operative analgesics agent(s) that will be used after surgery to control pain:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (mg/kg) &amp; Volume (ml)</th>
<th>Route</th>
<th>Frequency (e.g. times/day)</th>
<th>Duration (e.g. days)</th>
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   f. Complete the following table for other medications (such as fluids, antibiotics, anti-coagulants, and other pharmacological agents) that will be administered post-operatively.

<table>
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<th>Agent</th>
<th>Dose (mg/kg) &amp; Volume (ml)</th>
<th>Route</th>
<th>Frequency (e.g. times/day)</th>
<th>Duration (e.g. days)</th>
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15. **Frequency and Responsibility for post-operative care.** Complete items 15.a. -15.c. below, then proceed to item 16. The names and after-hours telephone (or other contact) numbers of the personnel listed below must be provided to the VMU staff in case of an emergency.

   a. Give the frequency of postoperative monitoring and how long the monitoring will continue:

   b. Who will be responsible for post-operative care until the animal can ambulate without danger to itself?

   c. Who will be responsible for post-operative care thereafter (including after-hours, weekends, and holidays)?

16. **Post-operative complications.** Complete items 16.a. - d. below; then proceed to item 17.

   a. Describe any possible or expected post-operative complications and what will be done if these complications arise:

   b. Provide criteria by which a decision to euthanatize a surgical patient post-operatively will be made:

   c. In case there is an emergency medical situation and you or your staff cannot be reached, identify drugs or classes of drugs that should not be used as part of the treatment plan:

   d. In the event that emergency euthanasia must be performed or an animal is unexpectedly found dead, how should the carcass be handled?

17. **Responsibility for maintaining animal post-surgical medical records.** Who will be responsible for maintaining accurate, daily, post-surgical written medical records?

   - My research staff or I will be responsible. Proceed to item 18 below.
   - The veterinary staff will be responsible. Proceed to item 18 below.
   - Local policy does not mandate that postoperative medical records be maintained for the species covered by this ACORP. **You have completed this Appendix. Do not answer item 18 or sign under item 18. Instead, go to item T on the ACORP.**
   - Other. Please explain, then proceed to item 18 below:

18. **Certifications.** Complete the following; then return to item T on the ACORP and continue.

   By my signature, I certify that

   - Each patient under observation or treatment will be identified such that care for individual animals can be documented.
   - Daily postoperative medical records of the patient will be maintained, including an evaluation of overall health, a description of any complications noted, treatment provided,
and the removal of sutures, staples, wound clips, or other such devices.

- Records will document administration of all medications and treatments given to animals, including those given to reduce pain or stress.
- As a minimum, daily records will cover the postoperative period as defined by local policy.
- Each entry in the records will include a signature or the initials of the person making the observation or treatment.
- All records will be readily available to the veterinary staff or the IACUC for review.
- The names and contact numbers of persons to notify or consult in case of emergencies will be provided to the facility manager and veterinarian.

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<th>Name of Principal Investigator(s)</th>
<th>Signature(s)</th>
<th>Date</th>
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**ACORP Appendix 6**

**SPECIAL HUSBANDRY AND PROCEDURES**

**VERSION 3**

1. **Special Husbandry.** Are special husbandry practices required for this protocol that are not described in the local Standard Operating Procedures (SOP) manual? Examples of special husbandry practices include temperature extremes, food or water deprivation, dietary manipulations, calorie restrictions, special housing/caging, modified light cycle, special health monitoring, and unusual means of identification.

   - [ ] No. Proceed to item 2.
   - [ ] Yes. Complete items 1.a. and 1.b.; then proceed to item 2.

   a. Provide a complete description of all non-standard practices or procedures. Make sure that the frequency and duration of these practices or procedures are stated:

   b. Justify the use of these non-standard practices or procedures:

2. **Other Procedures.** Are other procedures such as prolonged physical restraint, use of noxious stimuli, forced exercise, behavioral manipulations, total or partial body irradiation, radiography or other imaging studies planned but not described elsewhere in the ACORP?

   - [ ] No. Proceed to item 3.
   - [ ] Yes. Complete items 2.a. and 2.b.; then proceed to item 3.

   a. Check all of the following procedures that are proposed:

      - [ ] Prolonged physical restraint, including chairing.
      - [ ] Noxious stimuli.
      - [ ] Forced exercise.
      - [ ] Behavioral manipulations.
      - [ ] Other. Describe:

   b. Describe each procedure and the expected outcome(s) in detail. Make sure that the frequency, duration, and interval between repeated manipulations are described:
3. In the table below, identify who will perform the procedures and practices listed in items 1 and 2 and who will be responsible for monitoring the condition of these animals. After-hours telephone (or other contact) numbers of the personnel listed must be provided to the veterinary staff in case of an emergency.

<table>
<thead>
<tr>
<th>Person</th>
<th>Role (performing procedure/monitoring)</th>
<th>Office Phone</th>
<th>Pager or cell phone</th>
<th>After-hours contact number</th>
<th>E-mail address</th>
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4. Do these practices or procedures have the potential to cause more than momentary pain and/or discomfort?

☐ No. You have completed this appendix; no further information is required in this appendix. Go to item W on the ACORP.

☐ Yes. Describe the potential pain and/or discomfort here; then proceed to item 5:

5. Will pain or stress-relieving agents be administered to the animals that experience pain and/or discomfort? Then proceed to item 6.

☐ No. Provide a scientific justification for not using pain or stress relieving agents here:

☐ Yes. Fill out the table below.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (mg/kg) &amp; volume (ml)</th>
<th>Route</th>
<th>Frequency (e.g. times/day)</th>
<th>Duration (e.g. days)</th>
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6. Describe the methods used to monitor the condition of the animals during and after the procedures and the criteria that will be used to remove individual animals from these procedures should pain or suffering be present:

7. Proceed to item W on the ACORP.

ACORP Appendix 7
REQUEST TO USE PATIENT CARE PROCEDURAL AREAS FOR ANIMAL STUDIES
Version 3

1. Name of Principal Investigator(s):
2. Provide a concise statement of the potential benefit to VA patients if a patient care area is used for research involving animals.

3. Why can’t the animal facility or a laboratory area be utilized for the proposed procedures?

4. Identify the species and number of animals to be used.

5. Discuss the potential pain and/or distress to animal subjects during the procedures to be conducted in a patient procedural area, and interventions planned for the prevention or alleviation of such pain/distress.

6. Identify the equipment and location (building and room numbers) of the patient care area(s) to be used.

7. List the date(s) and time of day that the procedure(s) will be performed.

8. Discuss the method of transporting the animals to and from the procedural area. Include a description of the transport containers, any vehicles used, and precautions to be taken to avoid contact with patients, visitors, and other non-research personnel.

9. Provide a complete description of the measures to be taken to prevent the transmission of zoonotic pathogens from animals to patients and patient care personnel.

10. Provide a complete description of the measures to be taken to prevent disturbances (e.g., noise, odors) to patients and patient care personnel.

11. Provide a complete description of methods to be employed to prevent contamination of equipment and room surfaces by animal feces, urine, saliva, blood, or other body fluids.

12. Provide details of the procedures to be followed in cleaning and disinfecting equipment and room surfaces following use.

13. Required signatures. (If this appendix is part of an ACORP, return to item X.3. on the ACORP.)

   a. Principal Investigator(s) submitting this request.

<table>
<thead>
<tr>
<th>Name(s) of Principal Investigator(s) (typed)</th>
<th>Signature(s)</th>
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   b. Approving officials.
ACROP Appendix 8
REQUEST TO USE EXPLOSIVE AGENT IN THE ANIMAL FACILITY OR IN ANIMALS
VERSION 3

1. Principal Investigator(s):

2. Give the name(s), title(s), and prior pertinent training and experience of individuals who will administer the explosive agent.

3. Name of the explosive agent(s), and the Material Safety Data Sheet number(s):

4. Why can’t a non-explosive agent or agents be used instead?

5. Give the beginning and ending dates during which the explosive agent(s) will be used.

6. Give a brief description of the studies for which the use of an explosive agent is proposed.

7. Give the species, weight, and approximate number of animal subjects that will be administered the explosive agent(s).

8. Give the building and room number in which agent(s) will be used.

9. Give a detailed description of the procedure(s) involving the explosive agent(s) including assurances that: a) procedures are performed within a properly operating, ventilated safety hood, b) all electrical equipment used with the agent are placed and powered outside the hood, c) once the seal is broken on containers of ether or other explosive anesthetic agents, they will be placed into a safety hood throughout use, stored in an explosion proof refrigerator or other approved storage area, and discarded properly once completely used, and d) that proper
disposal procedures for items (including carcasses) containing traces of the agent will be safe and appropriate. (When finished, proceed to item Y on the ACORP.)

10. Required signatures.

a. Principal Investigator(s) submitting this request.

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<th>Name(s) of Principal Investigator(s) (typed)</th>
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b. Approving officials.

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<tr>
<th>Name of IACUC Chair (typed)</th>
<th>Signature</th>
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<tr>
<td>Name of Attending Veterinarian (VMO or VMC, typed)</td>
<td>Signature</td>
<td>Date</td>
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<tr>
<td>Facility Safety/Biosafety Officer (typed)</td>
<td>Signature</td>
<td>Date</td>
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<tr>
<td>ACOS for R&amp;D (typed)</td>
<td>Signature</td>
<td>Date</td>
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<tr>
<td>VISN Regional Safety Officer (typed)</td>
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**ACORP Appendix 9**  
**LSCDVAMC RODENT BREEDING APPENDIX**

Instructions. The purpose of this appendix is to account for rodents used as part of a breeding colony. Follow the instructions carefully.

1. Fill out the following table for each strain you plan to breed.

<table>
<thead>
<tr>
<th>Strain designation</th>
<th>Mutation, transgene, or other genotypic manipulation</th>
<th>Source of breeders (commercial supplier, institution, etc.)</th>
<th>Microbial status (e.g. unknown, SPF, known infections)</th>
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2. Describe the breeding scheme for each strain that will be bred. Indicate how many females per male will be housed, and the mating system planned (brother-sister mating, back-cross, etc).

3. Who will wean the mice and choose the next generation of breeders?

4. At what age will breeders be started and retired?

5. At what age the mice will be weaned?

6. Describe the characteristics of each particular strain that result from the genotype, including any detrimental impact on the immune system or other clinical problems or anomalies.

7. Personnel and Qualifications. Give the name(s) of all individual(s) who will work with the breeding colony, and describe their relevant education, training, and experience with breeding animals.

8. If personnel do not have experience, how will they be trained and by whom?

9. Will tail snips or other tissues for genetic testing be required to maintain the colony? If so, describe all tissue collection procedures, including the use of local or general anesthesia used prior to tissue collection.

<table>
<thead>
<tr>
<th>Tissue or fluid collected</th>
<th>Site &amp; method of collection</th>
<th>Amount (g) or volume (ml)</th>
<th>Anesthetic Agent</th>
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10. Complete the following table, using your best estimates of yearly needs. Average the figures over the next three years.

<table>
<thead>
<tr>
<th>Strain</th>
<th>Number of breeders needed per year</th>
<th>Number of weanlings that will be euthanized because of improper genotype or gender per year</th>
<th>Number of breeding cages needed per year</th>
<th>Number of weanlings that will be used in experiments per year</th>
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Note- breeders and weanlings that will not experience any potentially painful tissue collections for genotyping, such as tail snips, and will not be used in any experiments should be placed in USDA pain/distress category B in item I on the main body of the ACORP. Breeders and weanlings that will experience potentially painful tissue collections should be placed in USDA pain/distress category D in item I. Mice in the last column should be placed in the USDA pain/distress category appropriate for them based upon experimental procedures that they will undergo.

11. Describe how the number of breeding animals needed for the study was determined.

12. Give the location (room number and facility) where the breeding colony will be located.
ACUP SOP Appendix 4
Minor Amendment Form

LSCDVAMC INSTITUTIONAL ANIMAL CARE & USE COMMITTEE
MINOR CHANGE IN ACTIVITY

I request an amendment to the animal use protocol for the above project by additions, deletions or changes in: (check all that apply):

☐ Animal strain [Complete item 1]
☐ Gender of animals listed on ACORP [Complete item 1]
☐ Number of animals (additions limited to 10% of number previously approved for non-USDA regulated species) [Complete item 1]
☐ Location for non-surgical animal procedures [Complete item 2]
☐ Location for rodent surgery (added locations must already be approved for survival or non-survival surgery) [Complete item 2]
☐ Intra-operative procedure that does not involve hazardous agents, sedation, anesthesia, analgesia, neuromuscular blockade, or antimicrobial therapy (additions may not alter invasiveness of procedure) [Complete item 3]
☐ Personnel (Limited to changes not involving a change in PI, or for personnel already approved for equivalent procedures in another ACORP) [Complete item 4]
☐ Personnel roles (Limited to personnel roles not involving the role of PI or addition of roles not described for this individual in another ACORP) [Complete item 4]
☐ Collection of tissue after euthanasia [Complete item 5]

Signature:

Principal Investigator Date

LSCDVAMC IACUC Action:
☐ Acceptable
☐ Acceptable pending clarifications
☐ Not Acceptable
☐ Defer to IACUC

LSCDVAMC IACUC Administrative Action

Chairperson: Date:

Version 7/09
1. **Change in animal strain, number or gender.**

<table>
<thead>
<tr>
<th>Add</th>
<th>Delete</th>
<th>Strain</th>
<th>Gender</th>
<th>Number approved</th>
<th>Number to be added</th>
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Justification for added strain, and identification of strain not specified above:

Justification for additional animals, including experimental groups and the basis for group sizes

2. **Change in location for approved animal activity.**

<table>
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<tr>
<th>Add</th>
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<th>Building</th>
<th>Room</th>
<th>Activity</th>
<th>Species involved</th>
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Justification/Reason for the change in location, & identification of location, activity, or species not specified above:

3. **Change in intra-operative treatment or procedure.**

**Add** treatment or procedure, described in detail, below:

**Delete** previously approved treatment or procedure below:

Justification/Reason for the change in intra-operative treatment or procedure:

4. **Change in personnel or personnel roles.** Describe the training if the new person will be performing invasive procedures on an animal, since none of the current training, web based or otherwise, constitutes hands-on training.

Addition and deletion of personnel (*attach Experience/Qualifications form for each person)*:

<table>
<thead>
<tr>
<th>Add</th>
<th>Delete</th>
<th>Name</th>
<th>Animal handling role in project</th>
<th>For IACUC / Training</th>
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Describe training for invasive techniques (including injections, surgery, tattooing, etc) for EACH person listed above.

Change in animal handling role for existing personnel:

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<tr>
<th>Name</th>
<th>New or additional animal handling role in project</th>
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Describe training for new techniques (including injections, surgery, tattooing, etc) for EACH person listed above.
5. Collection of tissue from euthanized animal - List tissue type(s):

<table>
<thead>
<tr>
<th>Species/Strain</th>
<th>Tissue to be Harvested:</th>
</tr>
</thead>
</table>

Principal Investigator, ACORP number & title that tissue harvest will be obtained from
PI: _____  Phone: _____  Email: _____  Protocol #: _____
Title: _____
ACUP SOP Appendix 5
Major Amendment Form

IACUC / Institutional Animal Care and Use Committee
CLEVELAND VA MEDICAL CENTER
AMENDMENT TO PROJECTS INVOLVING ANIMALS

Use this form to submit amendments to your currently approved ACORP. **Type or print all entries.** Complete items #1-5 on the form and answer items # 6-10 in a narrative form and submit the amendment to Jaime Shuster, M.A., M.P.H., Medical Research Service (151W).

1. Principal Investigator: Phone:
E-mail:

Signature: __________________________ Date:

2. Main Contact /Name: Phone: E-mail:

3. Protocol Number

4. Protocol Title:

5. Type of Amendment: Proposed change in (check all that apply):
- animal numbers
- use of stress or pain relieving substances or potentially hazardous substances
- animal use procedures
- personnel
- animal care procedures
- other (please specify in writing)
- animal species (please stop here and submit a new protocol)

Complete each of the following items in narrative form below or on separate pages. Write “N/A” if not applicable.

6. Describe and justify any proposed changes in the animal numbers listed in your approved protocol.

7. Describe and justify any proposed changes in the animal use procedures described in your approved protocol. Attach the appropriate Appendix from the ACORP.

8. Describe and justify any proposed changes in the animal care procedures described in your approved protocol. Attach the appropriate Appendix (most likely App 6) from the ACORP.

9. Describe and justify any proposed changes in the use of sedative, anesthetic, analgesic, or potentially hazardous substances, e.g. radioisotopes, hazardous chemicals, infectious agents, recombinant DNA (including, use or generation of transgenic animals). Attach the appropriate Appendix (3) from the ACORP and complete an amended research safety survey (http://www.cleveland.med.va.gov/res/rpss.htm) and submit along with the amendment.

10. For new personnel, attach their CVs or resumes and describe their qualifications. Provide the dates of their safety training, video/DVD animal training, mandated on-line training at http://www.cleveland.med.va.gov/res/IACUCtraining.htm. In detail, explain how they will be trained to perform animal procedures particular to this protocol.

**Reminder:** If new personnel are added to a protocol, they must complete new employee forms.
and safety training before they can participate in this protocol. Provide a copy of the protocol to all new study personnel and maintain documentation of training.

11. Describe any other proposed changes to your approved protocol.
## ACUP SOP Appendix 6
### Continuing Annual Review Form

**IACUC / Institutional Animal Care and Use Committee**

**LOUIS STOKES CLEVELAND DVAMC MEDICAL CENTER**

**Continuing Review Of Projects Involving Animals**

*Form Directions:* This form is protected (limited access to the fill-in fields). Use the tab key or mouse to navigate the fill-in fields. Formatting is limited in the text fields (no bulleted lists, numbering, etc). In the event that you are unable to navigate through the protected document or would like to format a document or add additional information, you may disable the protected feature by selecting “Tools” and “Unprotect Document.” Please do not delete or modify questions.

Principal Investigator: 
E-mail: 
Ext.: 
VA Protocol #: 
Protocol Title: 
Species/Strain: 
Project Approval Period: from through

1. **ANIMAL NUMBERS:**

<table>
<thead>
<tr>
<th>Category</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Animals Approved</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Number of Animals Used to Date:</td>
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<td></td>
</tr>
<tr>
<td>Number of Animals Used Since Last Review:</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Number of Animals Bred to Date:</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Number of Animals Bred Since Last Review:</td>
<td></td>
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</tr>
</tbody>
</table>

**USDA Category B:** 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.)

**USDA Category C:** 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.

**USDA Category D:** 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.

USDA Category E: 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. LD50, mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.

2. a. PROJECT STATUS

PROJECT IS:  
☐ ACTIVE/OPEN
☐ COMPLETED/CLOSED*

2. b. *Will work continue on this project without an animal component (If you are accessing VA Central Office funds under this project and wish to continue accessing these funds after closing this project please mark “Yes”)?

YES ☐ NO ☐

IF YES, please attach conflict of interest statements for each member associated with this study. This review and conflict of interest statements will be forwarded to the R&D committee.

3. Summarize your animal work on this project over the past year. Please indicate if you have encountered any problems or adverse events and how they were resolved. (Limit 250 words)

4. Have there been any problems with or changes* to the experimental design since the last IACUC review?  
YES ☐  NO ☐

IF YES, please explain:

* An amendment to the protocol and a modification of the appropriate ACORP Appendix must be submitted to the IACUC for review and approval before it can be initiated. Changes may include but are not limited to: changes in study objectives; proposal to switch from nonsurvival to survival surgery; changes in the degree of invasiveness of a procedure or discomfort to an animal; changes in the approximate number of animals used; changes in personnel involved in animal procedures; changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia; changes in the duration, frequency, or number of procedures performed on an animal.

5. Were all changes described above prospectively reviewed and approved by the IACUC prior to implementation?

☐ No problems or changes to report

☐ Yes (please provide the date(s) of IACUC approval):

☐ No (please explain):

6. Study Personnel (List all personnel that are currently working on this project.):
7. Please attach Conflict of Interest Statements for the principal investigator and co-investigator. Study personnel listed in Item (6) do not need to complete the Conflict of Interest Statement. This can be found at [http://www.clevelandvaresearch.org/committee_iacuc.htm#forms](http://www.clevelandvaresearch.org/committee_iacuc.htm#forms)
Investigator Assurances

I agree to abide by the policies of the Louis Stokes Cleveland DVA Medical Center Institutional Animal Care and Use Committee (IACUC) and all applicable federal regulations.

I will adhere to the protocol as described and as modified.

I will submit any modifications of the protocol to the IACUC for review and approval before initiating them.

I will notify the IACUC of changes in the location of the animal research.

I will assist the IACUC in verifying compliance with the regulations.

I will notify the IACUC of any unexpected results that affect the welfare of the animals. I will report any unanticipated pain or distress, morbidity, or mortality to the attending veterinarian and the IACUC.

I understand and agree that emergency veterinary care, including euthanasia, will be administered to animals exhibiting unbearable pain distress or illness. Prior to any emergency treatment, the veterinary staff will make every effort to contact my representative or me.

I declare that all experiments involving live animals will be performed under my supervision or that of another qualified scientist. All other personnel involved in animal use in this project have been or will be trained in proper procedures relevant to this protocol, including but not limited to animal handling, administration of anesthetics and analgesics, aseptic technique, postoperative monitoring, and euthanasia. I will notify the IACUC when new employees are hired and will certify when their training to perform the relevant experimental procedures on live animals is complete.

I understand that all data collected and protocol development associated with this project are the property of the Veteran’s Health Administration. These materials must be stored in accordance with Record Control Schedule 10-1 (http://vaww1.va.gov/vhapublications/).

I declare that the information provided in this protocol is accurate. I certify that this protocol accurately describes all procedures in which I intend to involve laboratory animal subjects.

I declare that the studies described here do not unnecessarily duplicate previous work by others or by me.

__________________________  ______________________
Signature of Principal Investigator  Date
7. SIGNATURES

__________________________
Nanette R. Kleinman, D.V.M.
Consulting Veterinarian

Date

OR

__________________________
Hector Munoz-Ramirez, D.V.M.
Consulting Veterinarian

Date

__________________________
Margot S. Damaser, Ph.D.
Chairperson, IACUC

Date

PLEASE SUBMIT THE COMPLETED FORM TO:

Jaime Shuster, M.A., M.P.H.
IACUC Coordinator
Medical Research Service 151(W)
VA Medical Center
10701 East Boulevard
Cleveland, OH 44106
CLEVELAND VAMC ANIMAL INCIDENT REPORT

This form is to be used to report incidents of non-compliance with appropriate standards of animal care and use. Any individual who engages in good faith disclosure of alleged wrongful conduct to a designated institutional official is protected against retaliation, harassment and adverse employment consequences per Whistleblower policy outlined in ACUP SOP 2.5.1. Any communication that proves to have been both unsubstantiated and made with malice or with knowledge of its falsity is not protected by this policy. This policy is also intended to protect individuals against false allegations of wrongful misconduct.

Please return the completed form to the Research Administrative Office (K-115).

YOU MAY CHOOSE TO REMAIN ANONYMOUS.

Date of incident: ____________________ Time of incident: ____________________
Animal species & identification: ____________________ Location: ____________________
Discovered by: ____________________ (You may choose to remain anonymous)
Describe incident: (PLEASE BE SPECIFIC AND INCLUDE THE NAME OF PERSONNEL INVOLVED.)

For office use only
Action Taken: ____________________

______________________________
______________________________
______________________________
______________________________

159
### Instructions
For each deficiency noted on this form, fill out a row in Form 2.

## PART A. PROGRAM REVIEW

**Date(s) of Review for VA Animal Care and Use Program:** <Date>

**Key**: NA = Not applicable, A = Acceptable, M = Minor Deficiency, S = Significant Deficiency

**Reference**: Section 2 in Appendix E, Handbook 1200.7, "Use of Animals in Research"

<table>
<thead>
<tr>
<th>Line #</th>
<th>Check list number and item description</th>
<th>Not Applicable</th>
<th>Acceptable</th>
<th>Minor</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I. IACUC POLICIES AND RESPONSIBILITIES</td>
<td></td>
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</tr>
<tr>
<td>2</td>
<td>IACUC Membership and Functions:</td>
<td></td>
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<tr>
<td>3</td>
<td>At least 5 members, appointed by the IO in writing for renewable terms</td>
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<td>4</td>
<td>Members include Attending Veterinarian, VA scientist, lay, and non-affiliated members</td>
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<td>5</td>
<td>Chairperson is appointed by Director for 1 yr. renewable term</td>
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<td>6</td>
<td>Reports to the R&amp;D Committee and the Institutional Official (IO) when appropriate</td>
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<tr>
<td>7a</td>
<td>Responsible for oversight and evaluation of institution's animal care and use program</td>
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<tr>
<td>7b</td>
<td>A formal MOU has been established 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.</td>
<td></td>
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<tr>
<td>8</td>
<td>IACUC conducts semiannual evaluations of the animal care and use program at the VA medical center</td>
<td></td>
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</tr>
<tr>
<td>9</td>
<td>IACUC either 1) conducts oversight and evaluation of the animal care and use program at all other institutions that house VA animals, or 2) the VA IACUC reviews and evaluates the semi-annual review of another IACUC in lieu of its own review of those programs</td>
<td></td>
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<tr>
<td>10</td>
<td>Conducts semiannual inspections of all VA animal facilities, laboratory</td>
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<tr>
<td>11</td>
<td>IACUC either 1) conducts oversight and evaluation of the animal care and use facilities at all other institutions that house VA animals, or 2) the VA IACUC reviews and evaluates the semi-annual review of another IACUC in lieu of its own review of those facilities.</td>
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<tr>
<td>12</td>
<td>IACUC semi-annual review includes all areas where animals are housed more than 12 hours, and all areas where procedures on animals are performed.</td>
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<tr>
<td>13</td>
<td>A veterinary consult is provided prior to IACUC review of protocols.</td>
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<tr>
<td>14</td>
<td>VA ACORP is used for review when applications will be submitted for VA funding (version 2 until January 1, 2005, version 3 thereafter).</td>
<td></td>
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<td>15</td>
<td>Procedures in place for review and approval of all VA-funded research regardless of performance location.</td>
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<tr>
<td>16</td>
<td>Procedures in place for review and approval of research performed at the VA, regardless of funding source (1200.7, 4.c.).</td>
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<td>17</td>
<td>Procedures in place for review and approval of significant changes to protocols before work begins.</td>
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<tr>
<td>18</td>
<td>Special procedures are reviewed prior to initiation (e.g. multiple surgeries, prolonged restraint).</td>
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<tr>
<td>19</td>
<td>Program/procedures in place for use of hazardous agents in animal research (see Section 7, Appendix C of 1200.7).</td>
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<tr>
<td>20</td>
<td>IACUC has procedures in place to review and investigate internal or external concerns or allegations about animal care and use (1200.7, 8.i.).</td>
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<tr>
<td>21</td>
<td>IACUC has procedures in place to prevent reprisals against whistle blowers who report potential deficiencies in the animal care and use program, and to protect anonymity to the extent required by law (see 1200.7 6.d. and references therein).</td>
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<td>22</td>
<td>IACUC has procedures in place for suspension of animal activities if warranted by findings and after majority vote of quorum (1200.7, 8.h.).</td>
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<tr>
<td>23</td>
<td><strong>II. IACUC REPORTING REQUIREMENTS</strong></td>
<td></td>
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<tr>
<td>24</td>
<td>IACUC minutes meet formatting requirements in 1200.7, paragraph 8.f.(1).</td>
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</tr>
<tr>
<td>25</td>
<td>IACUC minutes are submitted for review by VA R&amp;D Committee and IO, and upon request, to CVMO/VACO (1200.7).</td>
<td></td>
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<tr>
<td>26</td>
<td>Semiannual reports approved by the IACUC are reviewed during a meeting between medical center Director and IACUC representatives, then signed by medical center Director (1200.7, 8.d.(1)(e)).</td>
<td></td>
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<tr>
<td>27</td>
<td>IACUC semi-annual report is not altered by any local official once a majority of voting IACUC members has voted to approve the report, and local officials do not pressure IACUC members to change the wording of such reports to language more favorable to the institution. (1200.7 8.d.(1)(f)/(g)).</td>
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<tr>
<td>28</td>
<td>Semiannual Reports are submitted to CVMO within 60 days of review (1200.7, 8.d.(1)(e)).</td>
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<tr>
<td>29</td>
<td>Minority IACUC opinions are included in semi-annual reports (1200.7, 8.d.(1)(d)).</td>
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<tr>
<td>30</td>
<td>Departures from Guide or PHS Policy are detailed, and reasons for departure are given.</td>
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</tbody>
</table>
31 Significant deficiencies are distinguished from minor deficiencies in semi-annual report

32 The semi-annual report include a plan and schedule with dates for correction of all deficiencies

33 IACUC notifies ACOS/R&D, IO, ORO, CVMO, USDA, PHS, and AAALAC within 15 days business days of finding instances of non-compliance (see 1200.7 8.g(5) and notes at the end of this form)

34 IACUC promptly notifies ACOS/R&D, IO, ORO, CVMO, USDA, PHS, and AAALAC within 15 days business days of suspensions of protocols (1200.7, 8.g(5))

35 IACUC notifies ACOS/R&D, IO, ORO, CVMO, USDA, PHS, and AAALAC within 15 days of failure to correct major deficiencies (1200.7, 8.g(5))

36 USDA Annual Report is submitted online to USDA

37 Mice and rats are not included in the USDA Annual Report but are included in VMU Annual Report per VA Policy (1200.7 8.j(1) and 8.j(4))

38 AAALAC Program Description submitted triennially to AAALAC (CVMO no longer receives copies routinely per 1200.7, 8.j(2)(a))

39 AAALAC Annual Report and other correspondence to and from AAALAC sent to CVMO (1200.7, 8.j(2)(b))

40 Annual VA VMU report sent to CVMO (1200.7, 8.j(4))

41 PHS Assurance, annual updates, and correspondence to and from OLAW sent to CVMO and ORO ((1200.7, 8.j(4) and 8.j(6))

42 III. IACUC RECORDS REQUIREMENTS

43 Minutes of IACUC meetings and semi-annual reports kept 3 years

44 IACUC documents, including all PHS, USDA, AAALAC, other reports and correspondence related to the animal care and use program are maintained at least three years, and IACUC records of individual protocols are kept at least 3 years after end of study

45 As part of the Program review, the IACUC randomly reviews IACUC records representing at least 5 percent of the total active projects (a minimum of five) to determine if appropriate documentation of initial review, approval letter(s), annual and triennial approvals, modifications, and investigator correspondence are present. (1200.7, 8.d(1)(b))

46 Emergency power is available to power HVAC equipment in the animal research facility in the event of an electrical outage, or an effective plan exists to provide supplemental cooling or other measures to maintain temperatures within the ranges dictated by the Guide for the Care and Use of Laboratory Animals. (1200.7, Appendix E, 3.b(8))

47 IV. PERSONNEL QUALIFICATIONS AND TRAINING

48 All personnel involved with animal research receive training to competently and humanely perform their duties related to animal research (1200.7, 8.k.)

49 Station has established and implemented an effective annual training program consistent with 1200.7, paragraphs 8.k(1)-(4), including subparagraphs

50 Includes professional/management/supervisory personnel

51 Includes animal care personnel
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>Includes investigators, instructors, technicians, trainees, students</td>
</tr>
<tr>
<td>53</td>
<td>Includes humane practices of animal care (e.g., housing, husbandry, handling)</td>
</tr>
<tr>
<td>54</td>
<td>Includes humane practices of animal use (e.g., procedures, anesthesia, surgery)</td>
</tr>
<tr>
<td>55</td>
<td>Includes research methods that minimize animal numbers</td>
</tr>
<tr>
<td>56</td>
<td>Includes research methods that minimize animal pain or distress</td>
</tr>
<tr>
<td>57</td>
<td>Includes use of hazardous agents and access to OSHA hazard notices</td>
</tr>
<tr>
<td>58</td>
<td><strong>V. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL</strong></td>
</tr>
<tr>
<td>59</td>
<td>OHS Program is established and complies with requirements of Section 10 of 1200.7 and Appendix C of 1200.7</td>
</tr>
<tr>
<td>60a</td>
<td>All personnel at risk of exposure to animal research hazards must enroll in an OHSP acceptable to OLAW and VA, regardless of whether they elect to utilize all available optional services. This includes all personnel whose duties result in exposure to animals (e.g., maintenance and engineering staff assigned to the VMU) as well as those 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. (1200.7, Appendix C, 3.a(1))</td>
</tr>
<tr>
<td>60b</td>
<td>Exposed personnel who decline optional VA OHSP services or participate instead in another OHSP (acceptable to OLAW and VA) provide documentation of this to VA.</td>
</tr>
<tr>
<td>61</td>
<td>Institution provides laundry service, uniforms, and all personal protective equipment needed free of charge to employees (1200.7, Appendix C, 5.a.)</td>
</tr>
<tr>
<td>62</td>
<td>OHSP program is based upon hazard identification and risk assessment (1200.7, Appendix C, 3.a(1))</td>
</tr>
<tr>
<td>63</td>
<td>Personnel training is provided as is appropriate for species used, and hazardous agents used (e.g., zoonoses, hazards, special precautions)</td>
</tr>
<tr>
<td>64</td>
<td>Husbandry and technical staff understand and use proper personal hygiene procedures during work (e.g. work clothing, laboratory policies)</td>
</tr>
<tr>
<td>65</td>
<td>Procedures in place for proper use, storage, and disposal of hazardous materials</td>
</tr>
<tr>
<td>66</td>
<td>Procedures in place to provide appropriate personnel protective equipment such as masks, respirators, gowns, eye protection, boots, etc.</td>
</tr>
<tr>
<td>67</td>
<td><strong>Program in place for annual medical evaluation and/or questionnaire review as described in Section 4 of Appendix C of 1200.7.</strong></td>
</tr>
<tr>
<td>68</td>
<td>A pre-employment evaluation is offered to employees to make sure the workplace does not pose unnecessary risks (1200.7, Appendix C, 3.a(2)(a))</td>
</tr>
<tr>
<td>69</td>
<td>Immunizations offered are appropriate (e.g. rabies, tetanus)</td>
</tr>
<tr>
<td>70</td>
<td>Zoonosis surveillance is appropriate for species housed (e.g. Q-fever, LCMV, parasites)</td>
</tr>
<tr>
<td>71</td>
<td>Procedures are in place for reporting/treating injuries, including bites, etc.</td>
</tr>
<tr>
<td>72</td>
<td><strong>Special precautions for personnel who work with primates:</strong></td>
</tr>
<tr>
<td>73</td>
<td>Tuberculosis screening includes all potentially exposed personnel</td>
</tr>
</tbody>
</table>
| 74 | Training and implementation of procedures is in place for bites and scratches, including procedures and supplies to immediately treat human
exposure to *C. herpesvirus*

<table>
<thead>
<tr>
<th>75</th>
<th>Education is provided regarding <em>Cercopithecine herpesvirus 1</em> (Herpes B) infections when susceptible primates are housed</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td><strong>VI. VETERINARY MEDICAL CARE</strong></td>
</tr>
<tr>
<td>77</td>
<td>Institutional arrangement is present with a veterinarian with appropriate lab animal qualifications</td>
</tr>
<tr>
<td>78</td>
<td>Backup veterinary care has been arranged</td>
</tr>
<tr>
<td>79</td>
<td>Veterinarian can access all animals and animal procedure areas as needed</td>
</tr>
<tr>
<td>80</td>
<td>Emergency/weekend/holiday veterinary care of animals has been arranged</td>
</tr>
<tr>
<td>81</td>
<td>Veterinarian oversees daily care of animals</td>
</tr>
<tr>
<td>82</td>
<td><strong>Veterinarian oversees disease prevention and control/quarantine program</strong></td>
</tr>
<tr>
<td>83</td>
<td>Veterinarian provides oversight/guidance for treatment of disease</td>
</tr>
<tr>
<td>84</td>
<td>Veterinarian provides oversight/guidance for surgery programs and pre/post-surgical care</td>
</tr>
<tr>
<td>85</td>
<td>Veterinarian provides oversight/guidance for anesthesia, analgesia</td>
</tr>
<tr>
<td>86</td>
<td>Veterinarian provides oversight/guidance for euthanasia procedures</td>
</tr>
<tr>
<td>87</td>
<td>Compliant drug control and storage procedures in place</td>
</tr>
<tr>
<td>88</td>
<td>Visits by part-time veterinarians are documented</td>
</tr>
</tbody>
</table>
### Part B. Facilities Review

**Date(s) of Facilities Review:** <date>

Key: NA = Not applicable, A = Acceptable, M = Minor Deficiency, S = Significant Deficiency

<table>
<thead>
<tr>
<th></th>
<th>VII. Laboratory Policies and Responsibilities</th>
<th>NA</th>
<th>A</th>
<th>M</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>89</td>
<td></td>
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<tr>
<td>90</td>
<td>Animal procurement from authorized vendors only</td>
<td></td>
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<tr>
<td>91</td>
<td>Primary enclosures, cage, or shelters are appropriate for species housed</td>
<td></td>
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<td></td>
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<tr>
<td>92</td>
<td>Social environment- appropriate for species housed</td>
<td></td>
<td></td>
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<tr>
<td>93</td>
<td>A compliant primate enrichment program exists</td>
<td></td>
<td></td>
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<tr>
<td>94</td>
<td>Exercise for dogs is provided when mandated by AWA Regulations</td>
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<tr>
<td>95</td>
<td>Special procedure policies (e.g. diet restriction, prolonged restraint) are conducted per IACUC approval</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>96</td>
<td>Use of specialized housing (e.g. barrier, isolation when appropriate) is utilized as approved by the IACUC</td>
<td></td>
<td></td>
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<tr>
<td>97</td>
<td>Food/water/bedding is appropriate for species housed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>98</td>
<td>Animal handling is appropriate for species housed</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>99</td>
<td>Cage/room sanitation is appropriate for species housed</td>
<td></td>
<td></td>
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<tr>
<td>100</td>
<td>Waste disposal meets facility, municipal, and federal policies and regulations</td>
<td></td>
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<tr>
<td>101</td>
<td>Animal identification is appropriate for species housed</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>102</td>
<td>Medical/surgical records are accessible and appropriate for species housed</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>103</td>
<td>Genetics/nomenclature of species are accurate on protocol forms and on cage cards</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>104</td>
<td>Animal transportation inside facility is discreet and compliant with institutional policy and paragraph 10.c.(3) of 1200.7</td>
<td></td>
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</tr>
<tr>
<td>105</td>
<td>Animal transportation between facilities is in climate controlled vehicles when appropriate and compliant with institutional policy</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>106</td>
<td>Emergency/holiday/weekend husbandry care of animals is provided</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VIII. Physical Facilities</td>
<td>NA</td>
<td>A</td>
<td>M</td>
<td>S</td>
</tr>
<tr>
<td>107</td>
<td>Procedural laboratories that house animals &gt;12 hours meet animal housing standards</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>108</td>
<td>All rooms and laboratories in which animal procedures occur are tracked by the IACUC during review for inclusion in the facilities review (see 1200.7, Appendix D, 1.q(1))</td>
<td></td>
<td></td>
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<tr>
<td>109</td>
<td>Specialized space (e.g. barrier, surgery, quarantine, necropsy) is maintained properly and safely utilized</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>110</td>
<td>Support facilities (cold storage, restrooms) are properly maintained and safely utilized</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>111</td>
<td>Facility maintenance problems are reported and corrected in a timely fashion</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>112</td>
<td>Ventilation is monitored to ensure adequate air changes and proper</td>
<td></td>
<td></td>
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<tr>
<td>114</td>
<td>HVAC motors, belts, and equipment is on a regular preventive maintenance program to prevent HVAC failures</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>115</td>
<td>At least annually, the IACUC tests the ability of facilities management personnel to properly detect and respond to elevations in animal room temperatures by purposely overheat a temperature sensor, then noting the response (1200.7, 7.b(2)(c) and subparagraphs)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>116</td>
<td>Reheat coils in animal rooms fail in the off position to prevent catastrophic overheating of animals (1200.7, 7.b(2)(a))</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>117</td>
<td>Air changes per hour in animal rooms meet standards in the <em>Guide</em></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>118</td>
<td>Directional air flow is proper to ensure a safe working environment and control of infectious agents</td>
<td></td>
<td></td>
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<tr>
<td>119</td>
<td>Air is flowing into the animal facility from outside areas to reduce allergen and pathogen exposure outside facility</td>
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<tr>
<td>120</td>
<td>Wall, ceiling and floor finishes allow appropriate sanitation</td>
<td></td>
<td></td>
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<tr>
<td>121</td>
<td>Paint on animal housing services is intact and not chipped or cracked</td>
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<tr>
<td>122</td>
<td>Ceiling tiles and plaster ceilings that experience water damage are replaced in a timely fashion to prevent mold growth</td>
<td></td>
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<tr>
<td>123</td>
<td>Requests for emergency facility repairs are addressed in a timely fashion by institutional personnel to prevent distress to animals and personnel</td>
<td></td>
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<tr>
<td>124</td>
<td>Temperature and humidity in animal rooms are monitored to ensure they stay within acceptable ranges</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>125</td>
<td>Temperature and humidity in animal rooms stay within normal ranges</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>126</td>
<td>Noise levels are controlled to prevent distress to animals and personnel</td>
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<tr>
<td>127</td>
<td>Facility cage, equipment and sanitation methods meets standards in <em>Guide</em></td>
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<tr>
<td>128</td>
<td>Cage wash and autoclave temperatures are monitored to meet applicable standards in the <em>Guide</em></td>
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<tr>
<td>129</td>
<td>Room care records document that husbandry staff observe animals on a daily basis and clean and water animals as is appropriate</td>
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<td>130</td>
<td>Soiled bedding disposal procedures are appropriate</td>
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<tr>
<td>131</td>
<td>Infectious waste generated by animal experiments is handled appropriately</td>
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<tr>
<td>132</td>
<td>Vermin control measures are adequate, and do not unnecessarily compromise animal and human health or scientific studies</td>
<td></td>
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<tr>
<td>133</td>
<td>Security measures meet applicable VA policies (see 1200.7, 7.k.)</td>
<td></td>
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<tr>
<td>134</td>
<td>Human injuries sustained in the animal facility are reported immediately and submitted for medical examination.</td>
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</tbody>
</table>
### IX. List of Investigator Laboratories, Holding Areas, and Procedure Areas Outside the Animal Facility Where Animals are Utilized, Manipulated, or Housed

<table>
<thead>
<tr>
<th>Location</th>
<th>Investigator(s)</th>
<th>Species utilized, brief description of procedures</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

### X. Work Orders

Summarize in the table below all work orders that were open at any time in the period since the last semiannual evaluation. Include all work orders submitted in this period, as well as any work orders that were submitted in any previous period but were not yet complete at the time of the last semiannual evaluation.

1) Sort the work orders into two Groups, those that address deficiencies that were noted in a semiannual evaluation (Group 1, below) and those that address other matters (Group 2, below).
2) For each work order that has been completed, calculate the number of days elapsed from the date the work order was submitted to the date the work was completed. Summarize the work orders
according to whether they were completed within 30 days of submission, they were completed in 30-60 days, or completion took more than 60 days.

3) Enter the work orders into the table below, according to the Group and the number of Days to Completion of the work. For each work order, enter a local reference ID number (so that further information about the work order can be accessed if necessary, and to allow tracking of work orders from one semiannual evaluation to the next), and the date on which it was originally submitted.

4) Enter into the last row of the table, any work orders that are currently not complete.

5) For each range of Days to Completion, for each Group, enter the total number of work orders.

6) Below the table, enter any comments that the IACUC wishes to document with regard to any of these work orders (e.g., circumstances responsible for delays, expected time needed for completion).

<table>
<thead>
<tr>
<th>Days to Completion of Corrective Action</th>
<th>Group 1 Work Orders Addressing Deficiencies Noted in Semiannual Evaluation</th>
<th>Group 2 Other Work Orders Submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrective Action Completed in &lt; 30 Days</td>
<td>Local Reference ID</td>
<td>Original Date of Submission</td>
</tr>
<tr>
<td>Corrective Action Completed in 30-60 Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective Action Completed in &gt;60 Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completion of Corrective Action Currently Pending</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total # of Work Orders:

Total # of Work Orders:

Comments:
Important Regulatory Notes

Question: What must be covered by the semi-annual IACUC self-assessment?

Answer: The semi-annual self-assessment must include all VA facilities and investigator areas where laboratory animals are used in procedures or housed for more than 12 hours. It must also include all facilities and programs which house animals purchased with VA funds (see paragraph 3.c. in VHA Handbook 1200.7). If the animals are housed in a satellite/affiliate facility, a formal arrangement may be made between the VA IACUC and the facility such that the VA IACUC may review that facility's semi-annual self-assessment as an IACUC business item instead of sending a VA IACUC team to inspect that facility and program. If the VA IACUC does not set up this type of agreement, the facility and its animal care and use program must be evaluated as part of the VA IACUC semi-annual self-assessment report.

Question: What is a significant deficiency?

Answer: Nearly identical definitions of a significant deficiency are found in the USDA AWA Regulations and PHS Policy. The two definitions are below:

1. USDA Animal Welfare Act Regulations, 9 CFR Part 2, Subpart C, Section 2.31, par. (c)(3): “A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”

2. Public Health Service Policy on Humane Care and Use of Laboratory Animals, IV. Implementation by Institutions, paragraph B.3: “…A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency…”

Question: Does the IACUC have to report significant deficiencies?

Answer: It depends. If the plan to correct a significant deficiency is not completed according to the schedule set by the IACUC in Form 2 (TABLE of PROGRAM and FACILITIES DEFICIENCIES) and approved by a majority of a quorum, the USDA AWA Regulations state that the failure to correct must be reported in writing within 15 business days by the IACUC, through the Institutional Official, to USDA and any Federal agency funding that activity (USDA AWA Regs, 9 CFR Part 2, Subpart C, Section 2.31, par (c)(3)). PHS Policy does not have the same requirement to report a failure to adhere to the correction schedule for a significant deficiency, but PHS Policy does require that the following be reported by the IACUC through the IO to PHS, regardless of whether a corrective plan is completed according to schedule:

- any serious or continuing noncompliance with PHS Policy (including the Guide for the Care and Use of Laboratory Animals).
- any suspension of an activity by the IACUC.

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Thus, if a deficiency is considered a significant one using by the IACUC and IO, consideration should be given as to whether it also qualifies as "any serious or continuing noncompliance with PHS Policy." For assistance, contact the Chief VMO for the VA (Michael.fallon@med.va.gov).

*Remember that the CVMO must be copied on all correspondence regarding animal compliance issues.*

**Question: Where can I get a clean copy of this form?**

**Answer:** Go to the "Animal Research" documents/references link at www.researchtraining.org for a copy you can download.
# Form 2. TABLE of PROGRAM and FACILITIES DEFICIENCIES

**February 2011 Version**

Instructions: For each deficiency noted on Form 1 (Checklist), enter the checklist number in the first column, and provide the information requested on this form. This form can also be used to track corrections afterwards (see last column). After Form 1 and 2 are complete, fill out Form 3 (Post-Assessment Documentation).

<table>
<thead>
<tr>
<th>Line # from first column, Form 1</th>
<th>Location</th>
<th>Description of Deficiency, Reason(s) for the Deficiency, and Plan for Correction</th>
<th>Type of Deficiency</th>
<th>Timetable For Correction (e.g. 30, 60, 90 days)</th>
<th>Date of Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Minor</td>
<td>Significant</td>
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</tr>
</tbody>
</table>
A. DOCUMENTATION of REVIEW TEAM (minimum of three members for program review, and three members for facility review; add more rows as needed):

<table>
<thead>
<tr>
<th>Typed Name</th>
<th>Role on IACUC (chair, veterinarian, scientist, lay member, non-affiliated member)</th>
<th>Indicate Participation in:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Program review</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

B. DOCUMENTATION of MINORITY OPINION(S). Any member who wishes to provide a minority opinion MUST be allowed to do so. Did any member wish to submit a minority opinion?

_______ Yes _________ No  If "yes", fill out section E below.

C. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. A majority of all voting members (not a majority of a quorum) must approve and sign the report. The report must be completed within one month of the self-assessment to facilitate IACUC review of the report.

By our signatures, we verify that 1) we have reviewed and approved Forms 1 (Checklist) and 2 (Table of Deficiencies), 2) we have read any minority opinions appearing in item D of this report, and 3) we hereby authorize IACUC representatives to review this report with the Medical Center Director:

<table>
<thead>
<tr>
<th>TYPED NAME</th>
<th>ROLE ON IACUC (chair, veterinarian, scientist, lay member, non-affiliated member)</th>
<th>2 signature</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
D. **Statement of AAALAC Accreditation** (reference: PHS Policy on Humane Care and Use of Animals, par. IV.B.3). Are all of the facilities and programs covered by this review accredited by AAALAC?

____Yes  _____No. If no, describe which portions of the facilities and program are not accredited below:

E. **MINORITY OPINION(S).** If part B is checked "yes", provide the typed minority opinion(s) here:

F. **COMMUNICATION WITH MEDICAL CENTER DIRECTOR.** VHA Handbook 1200.7 paragraph 6.n(10)(a)5 stipulates that after a majority of all voting IACUC members approve the report and indicate their approval by signatures next to their typed names and roles on the committee, the report must be discussed with the Medical Center Director by the VMO/VMC, the IACUC Chair, and the ACOS/R&D (other IACUC members may also attend), and the Medical Center Director must sign the reporting indicating that he/she has reviewed it. **Note: the Director's signature does not imply that he/she agrees with the report, but once approved by the IACUC, it may not be altered by any official.** A discussion of disputed items may be provided in a cover memo.

Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the IACUC.

<table>
<thead>
<tr>
<th>Typed Name of Director</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

G. **FINAL PROCESSING**

A signed copy of the complete report (including Forms 1, 2, 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the self-assessment date. 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 Xerox copy with all signatures to Dr. Michael Fallon, CVMO, Atlanta VA Medical Center, Research Service-151V, 1670 Clairmont Road, Decatur, GA 30033. The original must be retained for at least the last three years.
Demographic Information

1. Name: ________________________________ ____________________________ _______________  
   Last First Middle Initial

2. Social Security Number: ________________________________ ____________________________

3. Date of Birth: _____/ _____/ _____  4. Age: __________  5. Sex: M F (circle one)
   Month Day Year

6. Today's Date: ________/ ______/ ______  
   Month Day Year

7. Race: (Circle one) Asian Black Hispanic/Latino White Other: ___________________

8. Current Job Title: ______________________________________________________________________

Where do you work? (Specific Location) ______________________________________________________________________

Building: _________________________  Floor: ____________________________  Room number: _____________________

Telephone number: ________________________________  Extension ________________________________

Pager/Cell Number: ________________________________

Date you began this job: __________/_______  Date you began with this organization: ________ / _______
   Month Year Month Year

Work Status: (Circle one) VA Paid Employee WOC Contractor Student CWRU employee

* Are you enrolled in the Case Western Reserve University/UH health services for animal research? Yes No Not Sure

Hours employed: (Circle one) Full-Time Part-Time PRN

Current Allergic Symptoms

9. Please complete the below table for any symptoms you have experienced on a regular basis to include year of onset, whether the symptom is present now, and the times at which you are most troubled by the symptom? If you have NOT experienced any of the symptoms below please proceed to question 10.

(Please EXCLUDE any symptoms that are associated with a cold, flu or other illness)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Year of onset</th>
<th>Present now</th>
<th>Spring</th>
<th>Summer</th>
<th>Fall</th>
<th>Winter</th>
<th>No particular Season</th>
<th>Home</th>
<th>Work</th>
<th>No Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watery or itchy eyes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Runny or stuffy nose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Sneezing spells</td>
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<td>Frequent cough</td>
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</tbody>
</table>
Difficulty swallowing
Sputum production (excessive mucous)
Sinus problems
Frequent colds
Hives
Swelling of lips or eyes
Eczema
Wheezing/Chest tightness

If you answered “YES” to the following questions, please complete the additional questions in the enclosed boxes. Thank you.

**Atopic History**

10. Do you think you have ALLERGIES? YES / NO

If YES:

To what are you allergic: _____________________________________________________

What symptoms do you have when your allergies act up? _______________________
_________________________________________________________________________

11. Have you ever had HAY FEVER? YES / NO

If YES:

At what age did you first develop hay fever? _________________________________

When was the last time you were troubled by hay fever? _______/___________

Month Year

12. Has a physician ever told you that you have ALLERGIES? YES / NO

13. Have you ever had a SKIN TEST for allergens (not TB)? YES / NO

If YES:

If you were tested, to what were you allergic? _________________________________

14. Have you received ALLERGY SHOTS? YES / NO

15. Have you ever taken MEDICATIONS FOR ALLERGIES? YES / NO

If YES:

What medications?
_________________________________________________________________________

How Often?
_________________________________________________________________________
16. Has a physician ever told you that you have ASTHMA?  
   YES / NO

17. Have you ever had an attack of wheezing that made you short of breath?  
   YES / NO
   If YES:
   At what age did you have your first attack? ____________________
   Are you still occasionally troubled by these attacks? YES / NO
   Do you currently take medications for these attacks? YES / NO

18. Are you allergic or sensitive to things that cause skin rashes?  
   YES / NO
   If YES:  
   What causes rashes?
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

19. Is there anyone in your immediate family with ALLERGIES or ASTHMA?  
   YES / NO
   IF YES: (circle all that apply)
   Father Allergies Asthma Both
   Mother Allergies Asthma Both
   Sister Allergies Asthma Both
   Brother Allergies Asthma Both
   Child Allergies Asthma Both

Home Environment

20. Have you EVER had HOUSE PETS?  
   YES / NO
   If YES:
   Which animals? For how long?
   _____ Dogs
   ____________________________________________________________
   _____ Cats
   ____________________________________________________________
   _____ Other (specify):
   ______________
   ____________________________________________________________
   ____________________________________________________________
   ___
   ____________________________________________________________
   Are you (or were you) allergic to them? YES / NO
   Do you have house pets now? YES / NO

21. Do you smoke cigarettes or cigars?  
   If YES:
On average, how many do you smoke per day? ____________

How many years have you smoked? ________________

If NO:

Did you smoke cigarettes or cigars in the past? YES / NO

For how many years? ____________

When did you quit? (Month/Year) ____________

22. Do other members of your household smoke? YES / NO

23. Did your parents smoke when you were living at home? YES / NO

24. Are you taking any medications on a regular basis? YES / NO

Please list ALL medications (including herbal and vitamin supplements) you are currently taking on a regular basis and how often you take them.

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

Occupational History / Current exposure Information

25. Have you worked with laboratory animals before this job? YES / NO

If YES:

For how long? (total years) ____________

What types of animals? _________________________________________________

Were you allergic to any of the animals with which you worked? YES / NO

If YES, what type of animal(s)? _______________________________________

When was the onset of allergy? (Year or Month/Year) ________________

26. In your current job do you handle animals or their tissue, body fluids, or cages? YES / NO

27. Do you work in the animal room at least once a week?

If YES:

How many days per week do you work with the lab animals or their cages? (circle one) 
<1 1 2 3 4 5 More ________
During these days, **how many hours per day (on the average)** do you work with lab animals or their cages? (circle one)

<table>
<thead>
<tr>
<th>&lt;1</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>More ________</th>
</tr>
</thead>
</table>

If NO:

Over the past 24 weeks (about six months) **during how many weeks** have you had lab animal contact?

During these weeks, **how many days per week** have you worked with lab animals? (circle one)

<table>
<thead>
<tr>
<th>&lt;1</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>More ________</th>
</tr>
</thead>
</table>

On these days, **how many hours per day** have you worked with lab animals? (circle one)

<table>
<thead>
<tr>
<th>&lt;1</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>More ________</th>
</tr>
</thead>
</table>

28. **How many hours per week** do you usually have contact with the following species? (circle one choice for each listing)

<table>
<thead>
<tr>
<th>Species</th>
<th>How many hours per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea Pig</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Hamster</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Dogs</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Cats</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Rat</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Rabbit</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Marmosets</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Primates</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Mice</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Other________ (specify)</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
</tbody>
</table>

29. **How many hours per week** are you usually involved in the following activities? (circle one choice for each listing)

<table>
<thead>
<tr>
<th>Activity</th>
<th>How many hours per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handle dirty cages</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Return clean cages</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Receiving animals</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Breeding Room</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Holding Room</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Gavage or other dosing</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Weighing</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Sacrifice/Necrops</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Isolators</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Change bedding</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Other animal room housekeeping</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Isolated organ or tissue experiments</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Using animals or tissues/liquids</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
<tr>
<td>Outside animal facility</td>
<td>0 &lt;1 1-5 6-10 11-15 16-20 21 or more</td>
</tr>
</tbody>
</table>

30. **When working with lab animals or their cages how often do you do the following?**

(Chck one choice for each item)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Never</th>
<th>Less than &lt;1/2 time</th>
<th>Most of the time</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear gloves</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wear a dust/mist respirator</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wear other respirator</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Wear a gown/Tyvek unit  
Wear hair bonnets  
Wear show covers  
Wash hands after handling animals’  
Wear eye protection  

31. Do you get any of the following symptoms from working with laboratory animals or their cages? (Or have you ever had any of the symptoms in the past from working with laboratory animals or their cages. In other words, if you were not able to wear personal protective equipment, would you probably get these symptoms?). **If No**, go to question #32.

### If YES:

#### Which of the symptoms do you have? (Please check all that apply)

- Sneezing spells
- Runny nose or Stuffy Nose
- Watery or itchy eyes
- Coughing spells
- Wheezing/Chest tightness
- Shortness of breath
- Skin rashes or hives

#### Does personal protective equipment eliminate these symptoms?  
- YES  /  NO

#### Which of the following species causes any of these problems?

- Guinea pig
- Hamster
- Dogs
- Cats
- Mouse
- Rat
- Rabbit
- Marmosets
- Primates
  
  (Type: _________________________________)

  Other:  
  
  (Specify: ____________________________________________________________)

#### How soon after exposure to lab animals do these symptoms start? (Circle one)

- Less than 10 minutes
- 10 minutes to 1 hour
- 1 to 8 hours
- More than 8 hours

#### How long do they last?

- Less than 10 minutes
- 10 minutes to 1 hour
- 1 to 8 hours
- More than 8 hours

#### Do you take any medications for these symptoms?  
- YES  /  NO

32. **Are there any lab animals with which you cannot work because of allergy problems?**  

   **If YES:**
Which animal species? ________________________________________________________

How long have you been allergic to this (these) species? _____________________________

33. Have you ever changed jobs or working habits because of symptoms from handling animals? YES / NO

   Please explain: ____________________________________________________________

34. Aside from your own work, are lab animals used by others in the same room where you work? YES / NO

35. Have you ever had Tuberculosis disease (TB)? YES / NO

   Have you been tested for TB in the past year? YES / NO

   Results: Positive / Negative

   When was the test performed? _____________________________

   Are you receiving immunosuppressive therapy such as prednisone, steroids or anti-cancer drugs? YES / NO

   If yes, please list with amount:

   ________________________________________________________________

Some people have been immunized against TB with a vaccine called BCG. This may make your skin test positive forever.

   Have you received BCG? YES / NO Don’t know

36. Have you received a Tetanus booster in the past 10 years? YES / NO

   If yes, when did you receive the tetanus booster?

   __________________________________________________________

37. Have you received a Rabies vaccination (if applicable)? YES / NO

   If yes, please list date: ________________________________

   When was your last Rabies titer? Date: __________________________

   Results of your last Rabies titer? Immune: _________ Not Immune: ________

38. Have you ever received Hepatitis B vaccine? YES / NO Don’t know

   If you have already received the vaccine, please sign the following statement:

   I have received the Hepatitis B vaccine. I do not need immunization.

   _______________________________________________________________

   Signature                             Date

39. Have you ever received Hepatitis A vaccine? YES / NO Don’t know

40. Do you ever smoke, eat drink, apply cosmetics or handle contact lenses in animal handling rooms? YES / NO

   When working with animals, do you always wear:

   Gloves  Yes  No
   Mask    Yes  No
   Protective eyewear Yes  No
   Gown/lab coat Yes  No
41. Do you perform the following after handling animals at work?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash hands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shower/change clothing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been issued &amp; do you wear a respirator?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Risk of injury-Which animals will you have contact with (check all that apply)?

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Animals Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>Fish or amphibians</td>
</tr>
<tr>
<td>Mild Risk</td>
<td>Rats, Mice, Rabbits, guinea pigs, hamsters, gerbils, birds, and swine with mild risk of injury (primary bites, and scratches, zoonotic disease, but significant potential for allergies.)</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>Dogs, cats, sheep, cattle, goats and wild rodents with moderate risk of injury (primarily bites, scratches, kicks, and crushing), zoonotic disease (rabies, Q fever, Hanta Virus, bacterial and fungal infections), and significant potential for allergies.</td>
</tr>
<tr>
<td>Marked Risk</td>
<td>Non-human primates with marked risk of injury (primarily bites and scratches). Zoonotic disease (herpes B virus, tuberculosis, viral hepatitis, bacterial infections), bacterial or viral infections (class 2 or greater) used in research, and some potential for allergies.</td>
</tr>
</tbody>
</table>

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 notify my supervisor and go to Personnel Health or Urgent Care if I have a reaction/bite/scratch to any animal or agent within the Louis Stokes Cleveland VA Medical Center Research animal handling area.

I understand that I am expected to adhere to Federal Research/Occupational Health & Safety regulations and failure to do so will result in administrative action. I understand that I must re-submit the Animal Questionnaire and provide documentation upon changes to my health status.

I have received training by Research Services that included the use of personal protective equipment and counseling as to the potential risk of zoonotic diseases:

Print
Name:_________________________________________Signature:_____________________________________

Date:_________________________

Employee Health Provider or Medical Representative Signature:_____________________________________

Date:_________________________
ACUP SOP Appendix 10
Personnel Health Laboratory Animal Allergy Questionnaire – Follow Up Form

Louis Stokes Cleveland VA Medical Center
Personnel Health
Laboratory Animal Allergy Questionnaire – Follow-Up

* This form should be completed only by employees who have completed an INITIAL questionnaire in the past. The INITIAL questionnaire should be used as a baseline when evaluating responses to the questionnaire.

**Demographic Information**

1. Name: _______________________ _______________________ _____
   Last First Middle Initial

2. Social Security Number: _______________________________

3. Current Job Title: _______________________________

4. Work Status: (Circle one) VA paid employee WOC Student Contractor CWRU student
   * Since your last questionnaire, have you changed job title? Yes No
   If yes:
   Date of change? ___________________________
   Where do you work? _______________________________
   Location: ___________________________________________________________________
   Building: ___________________________________________________________________

   * If you are currently working at Case Western University Animal Research Lab:
   Are you currently enrolled or have you started your enrollment with Case Western Reserve Health Services
   Yes: _____ No: _____ Not Sure: _____

5. Are you currently pregnant? Yes No N/A Near future plans? ___________________________

6. Please list all current medications:
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________

**Current Allergic Symptoms**

7. Please list current allergies to: (Environment / Medications):
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________

8. Specific allergies to:
   _____ Cat  _____ Rabbit  _____ Guinea Pigs
   _____ Dog   _____ Mice   _____ Other Animal: (please list) _____________
**Occupational History**

9. **Total amount of contact hours/time at work with animals per day:** ________________________________

   List those animals you are exposed to outside of Home/work: ______________________________________

   Have you developed any disorders or illnesses since your last questionnaire/Personnel Health examination?
   If yes, Please explain___________________________________________________________

   Since your last physical examination has a physician diagnosed you with any allergies or pulmonary disease? (i.e. COPD, Asthma, RSV, etc.)
   Yes  No  Not Sure

   If Yes, Please explain____________________________________________________________________

10. **Have you ever had Tuberculosis disease (TB)?** Yes  No

   Have you been tested for TB in the past year?
   What were the results?  Positive  Negative
   When was the test performed? _______________________________________________________________

   Some people have been immunized against TB with a vaccine called BCG. This may make your skin test positive forever. Have you received BCG? Yes  No  Don’t know

   Are you receiving immunosuppressive therapy such as prednisone, steroids or anti-cancer drugs? Yes  No
   If yes, please list with amount: ___________________________________________________________

11. **Have you received a Tetanus booster in the past 10 years?** Yes  No

   When did you receive the Tetanus booster? (Date :) ____________________________________________

   Have you ever received Hepatitis A vaccine? Yes  No  Don’t know

   Have you ever received Hepatitis B vaccine? Yes  No  Don’t know

   Have you ever had Hepatitis B? Yes  No  Don’t know

   Have you ever been diagnosed with Hepatitis C? Yes  No  Don’t know

   Have you ever been diagnosed with Hepatitis C? Yes  No  Don’t know

   Have you ever been diagnosed with Hepatitis C? Yes  No  Don’t know

   Have you ever been diagnosed with Hepatitis C? Yes  No  Don’t know

   **COMPLETE THIS SECTION ONLY IF YOU WORK WITH ANIMALS AT THE LOUIS STOKES CLEVELAND VAMC THAT MAY HARBOR RABIES.** (This section only pertains to those individuals that the CDC recommends rabies vaccines for).

   If No / Not Applicable, Please check the Skip section below.

   **SKIP:** ______

12. **Have you received a Rabies vaccination (if applicable)?** Yes  No

   If yes please list date: _________________________

   When was your last Rabies titer? Date: _____________________

   Results of your Rabies titer: Immune: _______  Not Immune: _______

13. **Since you started working handling animals, have you experienced any of the following?**

   a. A change in your health status that may make you more susceptible to infection? Yes  No
b. A change in your pulmonary health status which may affect your use of a face mask?  Yes  No

---

**Personal Protective Equipment/Clothing and Hygiene Practices:**

14. Do you ever smoke, eat, drink, apply cosmetics or handle contact lenses in animal handling rooms?  Yes  No

If yes, please explain: ____________________________

15. When working with animals, do you always wear?

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mask</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protective Eyewear</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gown/lab coat</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. Do you perform the following after handling animals at work?

<table>
<thead>
<tr>
<th>Task</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash hands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shower/change clothing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been issued a respirator?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Do you wear a respirator?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

---

**Hypersensitivity:**

17. Do you have a history of hay fever, asthma, or allergic skin problems?  Yes  No

18. Do you have a family history of hay fever, asthma, or allergic skin problems?  Yes  No

19. Do you have sneezing, runny nose, watery or itchy eyes, coughing, wheezing, or SOB after working with the Animals or their cages?  Yes  No

If Yes, which species? ____________________________

If Yes, which symptoms? ____________________________

20. Do you have any house pets?  Yes  No

If yes, which type? ____________________________

---

**Risk of injury-Which animals will you have contact with (check all that apply)?**

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
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</tr>
<tr>
<td>Moderate Risk</td>
<td>Dogs, cats, sheep, cattle, goats and wild rodents with moderate risk of injury (primarily bites, scratches, kicks, and crushing), zoonotic disease (rabies, Q fever, Hanta Virus, bacterial and fungal infections), and significant potential for allergies.</td>
</tr>
<tr>
<td>Marked Risk</td>
<td>Non-human primates with marked risk of injury (primarily bites and scratches). Zoonotic disease (herpes B virus, tuberculosis, viral hepatitis, bacterial infections), bacterial or viral infections (class 2 or greater) used in research, and some potential for allergies.</td>
</tr>
</tbody>
</table>

---

I certify that this 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 also understand I must immediately go to Personnel Health or Urgent Care if I have a reaction/bite/scratch to any animal or agent within the Louis Stokes Cleveland VA Research Animal Handling area.
I understand that I am expected to adhere to Federal research/occupational health & safety regulations (VHA Handbook 1200.7; CFR Title 10, Part 20 and Title 29, Part 1910; MCP-PSCL-002) and failure to do so will result in administrative action. I understand that I must re-submit the Annual Questionnaire upon changes to my health status.

I have received training by Research Services that included the use of personal protective equipment and counseling as to the potential risk for zoonotic diseases.

Print Name: ___________________________________________________________________________________

Signature: ______________________________________________________________ Date: ___________

Personnel Health Provider or Medical Representative Signature: _______________________________________

Date: ___________________________________________________________________________________________
AUTHORIZATION TO ADOPT AN ANIMAL OWNED BY
THE LOUIS STOKES CLEVELAND DVA MEDICAL CENTER (LSCDVAMC)

Date: ______________________

APPLICANT: _____________________________________________________________

Address: ___________________________________________________________________

City: __________________________ State: ___________ Zip: ___________

ANIMAL IDENTIFICATION:
Species: __________ Sex: _______________ Age: __________

DESCRIPTION: (Include color, hair/coat description, approximate weight and any identifying numbers)

__________________________________________________________________________
__________________________________________________________________________

NUMBER OF PROTOCOL UNDER WHICH ANIMAL WAS USED ______________

PRINCIPAL INVESTIGATOR ____________________________________________

ACORP/STUDY TITLE _________________________________________________

CERTIFICATION OF PRINCIPAL INVESTIGATOR: As the principal investigator authorized by the Institutional Animal Care and Use Committee (IACUC) to use the animal described herein, I certify that said animal is no longer required for this research protocol and is available for adoption. Furthermore, I certify that this animal has not been infected with agents hazardous to humans or treated with any radioactive, biohazardous, carcinogenic or toxic substances that pose a risk to humans. This animal has / has not (circle) had surgery. If so, what procedure:

__________________________________________________________________________

SIGNATURE OF PRINCIPAL INVESTIGATOR: ________________________________

AGREEMENT:

I, _________________________________ , as identified as the applicant, wish to adopt the above described animal for the purpose of maintaining it as a pet, I confirm that I am knowledgeable about the routine care required for this animal. I agree to provide it with humane treatment and to seek veterinary care for said animal in accordance

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with commonly accepted veterinary practice. I agree that I will not use or dispose of the animal in any way for monetary gain.

I understand that once I adopt the animal, it may not be returned to LSCDVAMC, and that the LSCDVAMC will have no further responsibility for its care. All other veterinary care is my responsibility. I release the LSCDVAMC from all liability of any kind whatsoever arising from my adopting the animal.

SIGNATURE OF APPLICANT: ____________________________________________

AUTHORIZATION:

________________________________________________________________________
Nanette Kleinman, D.V.M.  
Consulting Veterinarian, LSCDVAMC  
Date

________________________________________________________________________
Neal Peachey, Ph.D.  
Associate Chief of Staff/Research  
Date