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I. INTRODUCTION

A. Purpose of Handbook

This Handbook has been created to give practical guidance in the management of research with animals at Columbia University (the University or Columbia). It is intended to be used as a general reference guide for faculty, staff and students at the University who are involved in research with animals. The Handbook will help faculty and staff to conduct research in accordance with applicable laws, governmental regulations and University policies.

Readers should be advised that recent policy enhancements or changes in sponsors’ policies and regulations may be more current than the contents of this Handbook. While every attempt will be made to keep this Handbook up-to-date, ultimately the most current information will be found in government regulations and by consulting the University’s Institutional Animal Care and Use Committee and/or Institute of Comparative Medicine.

B. Resources

The University has websites and other resources that provide a wealth of information to anyone doing research. The following describes those that are the most relevant to persons doing research with animals.

1. The Office of the Executive Vice President for Research (EVPR)

The Office of the EVPR’s website https://research.columbia.edu provides quick links to useful websites including:

- Institute of Comparative Medicine https://research.columbia.edu/content/institute-comparative-medicine
- Institutional Animal Care and Use Committee https://research.columbia.edu/content/institutional-animal-care-and-use-committee
- Sponsored Projects Administration http://spa.columbia.edu/
- Sponsored Projects Finance http://finance.columbia.edu/content/sponsored-projects-finance
- Research Compliance and Training https://research.columbia.edu/content/office-research-compliance-and-training
- Environmental Health and Safety http://ehs.columbia.edu
- Radiation Safety https://research.columbia.edu/content/radiation-and-laser-safety
2. Handbooks

In addition to this Handbook, the Office of the EVPR has produced the following Handbooks to provide guidance to faculty, staff and students at the University in matters relating to research. The Handbooks are available online and in pdf on the EVPR website.

- Sponsored Projects Handbook
- Clinical Research Handbook
- Research Environmental Health and Safety Handbook
- Research Radiation Safety Handbook

3. Rascal

Rascal is a web-based suite of information technology modules that was developed internally at the University to house many of the University’s research administration and compliance processes. Rascal can be accessed at: https://rascal.columbia.edu/.

There will be many references to Rascal in this Handbook. Currently, Rascal serves as the electronic system for the following:

Training and Certifications

Rascal houses a number of training courses and tracks compliance with training requirements. Many of the training courses relate to the use of animals and there are additional safety training courses that are relevant to research with animals. These include, but are not limited to, the following:

- Introduction to the Institute of Comparative Medicine
- Regulations and Guidelines Pertaining to Animal Research at Columbia
- Safety, Chemical Hygiene, and Hazardous Waste Management Refresher Training
- Radiation Safety (Annual Refresher Training for Research Principal Investigators and Lab Managers and/or Annual Refresher Training for Users of Radioactive Materials)
- Biological Safety/Bloodborne Pathogens Refresher Training
- Shipping Biological (Infectious and Potentially Infectious) Materials and Genetically Modified Microorganisms
- Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods
- Laser Safety Training
- The Safe Use of Formaldehyde
- Controlled Substances Use and Management in Research
• Recombinant DNA and NIH Guidelines Training
• Viral Vector Research – Handling and Biosafety
• Biological Safety Cabinet Training

See **Getting Started: Training (Chapter II)** for additional information on training.

**Institutional Animal Care and Use Committee (IACUC)**

Rascal is used by investigators to create IACUC protocols and by the IACUC to administer the protocol review process. See **Preparing for a Study: Protocol Preparation (Chapter III)** and **Preparing for a Study: IACUC Approval (Chapter IV)** for additional information on protocols and the protocol review process.

Rascal also links data from other modules that are needed to obtain IACUC approval of a protocol. The ones most relevant to animal research are:

- Hazardous Materials
  - Recombinant DNA
  - Infectious Agents
  - Human Source Material
  - Lasers
  - Hazardous Chemicals or Toxins
  - Use of Radiation in Animals
  - Controlled Substances
- Training Certifications

**Proposal Tracking**

Rascal routes electronic approvals of proposals or contracts required by Sponsored Projects Administration (SPA). These include Principal Investigator certifications and departmental and school approvals. See **Preparing for a Study: Review and Finalization of Proposals (Chapter V)**.

Any Columbia faculty or staff member or student may use Rascal. In addition, non-Columbia personnel who are acting as collaborators on a research project may be able to obtain a temporary UNI and be permitted access to Rascal if they have the proper credentials. You can obtain a UNI online at [https://cuit.columbia.edu/cuit/manage-my-uni](https://cuit.columbia.edu/cuit/manage-my-uni)

The first time you log into Rascal, you should complete a user profile and fill out an annual conflict of interest disclosure form. For more information on conflicts of interest, see **Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications – Financial Conflicts of Interest (FCOIs) (Chapter VI, Section E(1))** in the Sponsored Projects Handbook.
C. Annexes

This Handbook contains a number of Annexes; an Index of Annexes can be found following the text of this Handbook immediately prior to the Annexes. See Annex I-A for a Glossary of Acronyms and Abbreviations used in the Handbook.

D. Regulatory Framework

Anyone conducting research with animals should have a working knowledge of the laws, regulations and guidances relating to such research. During the past 40 years, there has been increasing public attention paid to the humane care and use of animals in research and this remains the primary purpose of the regulatory framework. The following is a brief outline of the most relevant laws, regulations and guidances; they will not be discussed in detail here and will be instead referenced throughout this Handbook as the subject requires.

1. U.S. Animal Welfare Act (AWA)

The AWA was first enacted in 1966 as Public Law 89-544 (7 USC 54) and has been amended a number of times. It is the primary federal law that regulates the treatment of animals in research, teaching and testing. The AWA defines “animal” as any live or dead warm-blooded animal, excluding birds, rats of the genus *Rattus* and mice of the genus *Mus*, bred for use in research and agricultural animals used for agricultural research (USDA Animals).

The U.S. Department of Agriculture (USDA), through the Animal and Plant Health Inspection Service (APHIS), is the responsible agency for implementing and enforcing the AWA and has issued extensive Animal Welfare Regulations (9 CFR 1, Subpart A) (the AWA Regulations).

In general, the AWA and the AWA Regulations require research facilities using regulated animals to do the following:

- Register with APHIS and provide their animals with proper treatment and a healthy and safe environment.
- Employ an attending veterinarian and establish a program of veterinary care.
- Establish an IACUC to oversee the humane care and use of animals and to review research protocols to ensure that they comply with AWA requirements.
- Provide training to all personnel involved in research projects in the humane care and handling of the species they work with.
- Address any reported animal welfare concerns.

The AWA directs APHIS to conduct periodic inspections and, if necessary, levy fines and commence enforcement actions. APHIS officials conduct unannounced inspections of research facilities at least annually to ensure compliance with the AWA.
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals

The Health Research Extension Act of 1985 (Public Law 99-158) provides the legislative mandate for the Public Health Service Policy on Humane Care and Use of Laboratory Animals (the PHS Policy). The PHS Policy implements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training that were promulgated in 1985.

The PHS Policy is applicable to all activities involving animals that are conducted or supported by the U.S. Public Health Service (PHS), the U.S. Department of Health and Human Services (HHS) or the National Science Foundation (NSF), whether the activities are performed at the University or at any other institution, within or outside the United States. For example, all research funded by the National Institutes of Health (NIH) is covered by the PHS Policy. It is the policy of the University that all research with animals, whether or not funded by PHS, HHS or NSF, must be conducted in accordance with the PHS Policy.

The PHS Policy defines an “animal” as “any live vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes” (PHS Policy, Section III). Unlike the AWA, the PHS Policy covers birds, fish, amphibians, reptiles, and laboratory rats and mice.

The administration and coordination of the PHS Policy is the responsibility of the Office of Laboratory Animal Welfare (OLAW), a division of the NIH.

In general, the PHS Policy requires any institution funded by PHS to:

- Provide a written Animal Welfare Assurance (Assurance) acceptable to the PHS setting forth compliance with the PHS Policy.
- Establish an institutional program for animal care and use (the Program).
- Appoint and support an IACUC to oversee the institution’s Program, facilities and procedures.
- Provide animal care according to the standards set forth in AWA and the Guide for the Care and Use of Laboratory Animals.
- Provide adequate veterinary care by a veterinarian with the appropriate authority and responsibility.
- Provide formal or on-the-job training for personnel who care for or use animals.
- Provide an occupational health program for personnel who work in laboratory animal facilities or have frequent contact with animals.
- Report to OLAW any serious or continuing noncompliance with the PHS Policy, serious deviation from the provisions of The Guide for the Care and Use of Laboratory Animals and suspension of an activity by the IACUC.
An institution’s Assurance is a commitment by the institution to comply with the PHS Policy, the Guide for the Care and Use of Laboratory Animals, the AWA and the Animal Welfare Regulations.

The University has a single University-wide program for the care and use of animals (the University Program) and a single IACUC under a single Assurance (the University Assurance) covering Columbia University Irving Medical Center (CUIMC), the Morningside and Manhattanville campuses and Barnard College (Barnard).

3. Guide for the Care and Use of Laboratory Animals

The Guide for the Care and Use of Laboratory Animals (the Guide) is a widely accepted primary reference on laboratory animal care. The Guide was written under the auspices of the Institute for Laboratory Animal Research of the National Academy of Sciences. PHS Policy mandates that institutions use the Guide as a basis for developing and implementing their Programs.

The Guide is intended to assist institutions in caring for and using animals in ways judged to be scientifically, technically and humanely appropriate. Included in the Guide are descriptions of institutional responsibilities and professional standards. Institutional responsibilities include monitoring animal care and use, provisions for veterinary care, training of personnel and the establishment of an appropriate occupational health and safety program. Professional standards encompass the animal environment, animal husbandry and management, veterinary care and design and construction of animal facilities.

4. AAALAC International (AAALAC)

AAALAC is a private, non-profit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. AAALAC accreditation is considered the gold standard for Programs and is only granted following review of the institution’s Program Description and a site visit. Accreditation is renewed every three years. The University Program is fully accredited.

5. New York State Department of Health

Columbia is subject to New York State Department of Health (NYS DOH) oversight and is regularly inspected by the DOH. The DOH uses the Guide as its regulatory framework for assessing the care and use of research animals.

E. Roles and Responsibilities

The primary oversight responsibilities within a Program rest with the Institutional Official, the Attending Veterinarian in the Institute for Comparative Medicine and the IACUC. Together they establish policies and procedures, oversee regulatory compliance, monitor Program performance
and support the highest quality research and humane animal use. The Principal Investigator also has responsibilities under the Program. The following briefly describes their roles and responsibilities.

1. **Institutional Official (IO)**

The IO is required to be a member of senior management of the institution and bears ultimate responsibility for the Program. The IO has the authority to allocate the resources needed to ensure the Program’s overall effectiveness and alignment of Program goals of quality animal care and use with the institution’s mission.

At Columbia, the EVPR is the IO for the University Program.

2. **Attending Veterinarian (AV)/Institute of Comparative Medicine (ICM)**

The AV is the University’s senior veterinarian responsible for the health and well-being of all laboratory animals used at the institution and oversees other aspects of animal care and use (i.e., husbandry, housing). The AV is the Director of the ICM, and in that capacity is responsible for the management and care of all animals at the University’s and Barnard’s animal facilities.

The mission of the ICM is to ensure the humane care of animals used in approved research and to support medical research teams in the development of new treatments for diseases. The ICM has veterinary specialists, including the AV, who are certified by the American College of Laboratory Animal Medicine (ACLAM), who direct the care and manage the health and welfare of animals at Columbia. They are assisted by clinical veterinarians and by other veterinary and animal care professionals.

3. **IACUC**

The responsibility of the IACUC is to oversee and routinely evaluate the Program. The members of the IACUC include practicing scientists, veterinarians, at least one member with a non-scientific background and at least one public member to represent general community interests. There is one IACUC at Columbia.

The IACUC’s oversight functions include:

- Reviewing the Program at least once every six months;
- Inspecting the University’s animal facilities at least once every six months;
- Preparing reports of its evaluations and submitting the reports to the IO;
- Reviewing concerns involving the care and use of animals at the University;
- Making written recommendations to the IO regarding any aspect of the University Program, facilities or personnel training;
• Reviewing and approving, requiring modifications in (to secure approval) or withholding approval of all protocols;
• Conducting continuing review of each previously approved, ongoing activity at least once every three years for non-USDA Animals and at least annually for USDA Animals; and
• Suspending an activity involving animals when appropriate.

See Preparing for a Study: IACUC Approval (Chapter IV) for a more detailed description of the duties of the IACUC.

4. Principal Investigator (PI)

The PI assumes full scientific, administrative and fiscal responsibility for the conduct of the study. His/her responsibilities with respect to research with animals include, but are not limited to, the following:

• Ensuring that all animal related activities for the PI’s studies are performed according to the specific IACUC approved protocols
• Ensuring that protocol renewals and modifications are submitted to the IACUC in a timely fashion
• Ensuring that all research personnel who conduct procedures on animals are eligible and qualified to do so on the animal species and in the areas used in the PI’s studies
• Ensuring that all research personnel working with animals on the PI’s studies are appropriately trained in animal welfare and hazard control
• Maintaining accurate clinical records, including information on experimental use, history of surgical procedures, use of anesthetics and analgesics and post-operative care
• Maintaining a program to ensure that drugs, chemicals and biological materials at or near their expiration are discarded
• Promoting, by example and instruction, a safe and environmentally sound workplace for all research personnel.

F. Summary of Laboratory Animal Oversight

The following is a concise summary of the regulatory framework for animal research:

<table>
<thead>
<tr>
<th>Regulation/Regulatory or Oversight Body</th>
<th>Main Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Welfare Act and Regulations</td>
<td>Covers research with all live or dead warm-blooded animals except rats, mice and birds bred for research and agricultural animals used for agricultural research.</td>
</tr>
</tbody>
</table>
Each research institution that uses a covered species must establish an IACUC to conduct semiannual inspections and Program evaluations and to review all animal experimental protocols.

The USDA registers research facilities and conducts unannounced inspections at least annually.

Violations may be punished with fines, cease and desist orders and registration suspension or revocation.

<table>
<thead>
<tr>
<th><strong>PHS Policy</strong></th>
<th>Covers research with all live vertebrate animals (including birds, fish, amphibians, reptiles and laboratory rats and mice) used in research funded by the PHS, HHS and NSF.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Each research institution provides a written Assurance of compliance with the PHS Policy and the Guide.</td>
</tr>
<tr>
<td></td>
<td>Each research institution that receives PHS, HHS or NSF funding must have the IACUC review all animal experimental protocols and conduct semiannual inspections and Program evaluations.</td>
</tr>
<tr>
<td></td>
<td>OLAW does not routinely conduct unannounced inspections, but all serious or continuing noncompliance with the PHS Policy, any serious deviation from the Guide and any suspension of an activity must be reported to OLAW by the IACUC.</td>
</tr>
<tr>
<td></td>
<td>Violations can result in institutional loss of PHS, HHS or NSF funding.</td>
</tr>
</tbody>
</table>

| **DOH** | Conducts announced annual inspections and evaluates the Program according to the Guide.                                                                                                                                                                    |

| **IACUC** | A committee, organized at every research institution subject to the AWA or the PHS Policy, which must review and approve or withhold approval of every proposed animal experimental protocol.                                                                 |
|           | Each animal protocol must include:                                                                                                                                                                                                                     |
|           |   • A justification for using animals, the number of animals to be used and the species chosen                                                                                                                                                        |
|           |   • The procedures or drugs to be used to eliminate or minimize pain, discomfort and distress                                                                                                     |
- A description of the methods and sources used to search for alternatives to painful or stressful procedures or, for non-USDA Animals, a discussion of alternatives that were considered, but not implemented for scientific reasons
- An assurance that the experiment does not unnecessarily duplicate previous research
- A clear and concise sequential description of the procedures involving the use of animals

Members must include at a minimum: a Chair, a veterinarian, a practicing scientist experienced in research involving animals, a member who is primarily involved in nonscientific endeavors (i.e., ethicist, lawyer, etc.) and a non-affiliated community representative (i.e., clergy, teacher, etc.).

IACUC members must inspect all of the institution’s research facilities and review its Program at least once every six months.

**AAALAC**

Nonprofit organization that accredits research facilities.

Accreditation is on a voluntary basis only.

Announced site visits are conducted every three years.
II. GETTING STARTED: TRAINING

A. Introduction

Prior to participating in any research using animals at the University or Barnard, all faculty, staff and students who are involved in such research (Animal Research Personnel) must be trained and appropriately qualified and experienced to conduct the proposed procedures on animals. The IACUC identifies all individuals who are required to be trained at the time of protocol review, notifies them of their training requirements and maintains the records of completion of training. If the IACUC has been notified that a new investigator will be coming to Columbia, it will provide him/her with an email checklist of required training prior to the investigator’s arrival. Certain training courses are mandatory and others are available as resources, but are not mandatory.

B. Mandatory Training

Please note that the Mandatory Training described in Sections 1-6 below is required for all Animal Research Personnel who are involved in research funded through Columbia, whether at the University, the New York State Psychiatric Institute (NYSPI) or Barnard, and references to “Animal Research Personnel” include all such persons.

1. Laboratory Animal Regulatory Training

All Animal Research Personnel are required to attend an orientation given by the IACUC that covers requirements of the PHS and USDA rules and regulations, general considerations regarding the humane care and use of animals, the concept of alternatives to the use of animals, and a general discussion of protocol review, as well as information on submitting animal welfare concerns.

The lecture is offered on a bi-weekly basis. Pre-registration is required due to space constraints. You can email the IACUC or go to the IACUC website for upcoming lecture times, registration instructions and locations.

In addition, all Animal Research Personnel are required to take the online course in Rascal entitled *TC2400: Regulations and Guidelines Pertaining to Animal Research at Columbia* at least once every three years.

2. Introduction to the Institute of Comparative Medicine

All Animal Research Personnel are required to complete an online course in Rascal entitled *TC0900: Introduction to the Institute of Comparative Medicine*. This course and its related quiz must be taken prior to taking any of the species specific training listed below.

3. Species Specific Training
All Animal Research Personnel are required to take species specific training (Species Specific Training). The Training is designed to provide Animal Research Personnel with practical experience and training in handling the animal species with which they will be working. The topics covered in the Species Specific Training include laws and regulations applicable to each specific species, basic animal restraint and handling techniques, zoonotic diseases, assessment of pain and distress, proper animal identification, anesthetic techniques, methods of gauging the depth of anesthesia and appropriate methods of euthanasia.

The ICM offers the following Species Specific Training courses that must be taken for each species that Animal Research Personnel plan to work with. The courses are administered through Rascal at https://www.rascal.columbia.edu/:

- TC0650: The Dog
- TC0750: The Pig
- TC0800: The Mouse and Rat
- TC0850: The Rabbit
- TC1000: The Ruminant
- TC1050: The Gerbil
- TC1051: The Guinea Pig
- TC1100: The Hamster
- TC1350: The Macaque
- TC1500: Fish
- TC1700: Xenopus Frogs
- TC3000: The Baboon
- TC3200: Avian
- TC4150: The Marmoset
- TC4700: The Squirrel Monkey
- TC5100: The Lizard
- TC5350: The Salamander
- TC5700: The Ferret

Taking the relevant Species Specific Training and passing the quiz in Rascal are prerequisites to hands-on wet lab training and to IACUC approval of any work with animals.

Researchers working with macaques must take TC0506: Macacine Herpes Virus -1 (aka Herpes B Virus) Training in Rascal prior to working with the monkeys and annually thereafter.

The ICM also offers hands-on Species Specific Training. Participation in the trainings requires prior medical surveillance approval. See Environmental Health/Medical Surveillance (Section D) below.

Completion of Species Specific Training is automatically recorded in Rascal.

4. Rodent Wet Lab Training
All Animal Research Personnel who work with rodents (mice and/or rats) (Rodent Handlers) are required to take species specific wet lab training (Rodent Wet Lab Training) conducted by the ICM training coordinator, under the direction of ICM veterinarians. The wet lab is designed to provide Animal Research Personnel with hands-on training in handling the animal species with which they will be working. The topics covered in the Rodent Wet Lab Training include basic principles of rodent handling, restraint, identification methods, blood collection, injections, anesthesia, perfusion and euthanasia. All procedures other than handling, restraint and intraperitoneal (IP) injection are performed on anesthetized mice. The procedures taught include: syringe use and safety, manual restraint (awake), ear punch, IP injection (awake), subcutaneous injection, intravenous injection, intradermal injection, oral gavage, submandibular bleeding, tail prick, use of a portable isoflurane anesthetic machine, injectable anesthetics, monitoring anesthesia, intracardiac blood collection, perfusion, CO2 euthanasia, cervical dislocation (mice) and bilateral thoracotomy.

The Rodent Wet Lab Training is offered on at least a weekly basis. Participation in the training requires prior medical surveillance approval. See Occupational Health/Medical Surveillance (Section D) below for additional information.

A Rodent Wet Lab Checklist is completed at the end of training by the instructor and signed by the trainee; samples of the Mouse Wet Lab Checklist and Rat Wet Lab Class Checklist can be found in Annex II-A-1 and Annex II-A-2, respectively.

You may sign up for the Training at https://cumc.co1.qualtrics.com/jfe/form/SV_dmAQN5GnxsVDweF.

The IACUC receives notification of your completion of Rodent Wet Lab Training.

Experienced Rodent Handlers may opt to take a Skill Assessment Wet Lab with the ICM training coordinator or one of the veterinarians. If in the judgment of the training coordinator or veterinarian, the Rodent Handler’s skills are not adequate, the Rodent Handler must take the Rodent Wet Lab Training. Skill assessments are given weekly or on an as needed basis.

5. Rodent Surgery Training

All Animal Research Personnel who perform, assist in or supervise rodent surgical procedures (Rodent Surgical Personnel) are required to take ICM wet lab training for rodent surgery (Rodent Surgical Training) conducted by the ICM. The training covers preparation of rodent surgery sites, sterilization of instruments, disinfection of skin, aseptic technique, pharmaceutical grade anesthetics, anesthesia monitoring, prevention of post-operative infections and other complications and analgesia.

Attending the Rodent Wetlab Training described in Rodent Wet Lab Training (Section 4) above, taking the online courses TC1550: Rodent Surgery and TC2750: Rodent Anesthesia and Analgesia in Rascal and passing the quiz are prerequisites for the course. In addition,
participation in the training requires prior medical surveillance approval. See Occupational Health/Medical Surveillance (Section D) below.

All Rodent Surgical Personnel are required to take the online courses TC1550: Rodent Surgery and TC2750: Rodent Anesthesia and Analgesia annually.

All Rodent Surgical Personnel who will be performing stereotoxic surgery are required to take the online course TC5200: Stereotoxic Surgery in Rodents annually.

You can sign up for Rodent Surgical Training at https://cumc.co1.qualtrics.com/jfe/form/SV_dmAQN5GnxsVDweF.

Advanced rodent micro-surgical training is available through the Department of Orthopedics and further information can be obtained at http://microsurg.hs.columbia.edu/.

6. Mouse Barrier Training

Animal Research Personnel who need access to the mouse barrier facilities must take TC0550: Rodent Barrier Training in Rascal and pass a quiz. After completing the online course and quiz, a hands-on building specific training session with the supervisor of the building where your animals will be housed should be scheduled via email. The training occurs weekly and must be completed before you are permitted access to the barrier facilities. Participation in the training requires prior medical surveillance approval. See Occupational Health/Medical Surveillance (Section D) below.

Animal Research Personnel must take TC0550: Rodent Barrier Training annually.

7. Facility Specific Orientation

Animal Research Personnel requiring access to a non-barrier animal facility at CUIMC or on the Morningside or Manhattanville campuses are required to take Building Specific Orientation presented by the applicable ICM facility supervisor. The training occurs weekly. This hands-on session consists of facility orientation and a training on biosecurity requirements and physical hazards inherent in the facility.

To schedule an orientation, contact the applicable facility supervisor.

8. Environmental Health and Safety (EH&S)

The principal training courses required for Animal Research Personnel who use or are exposed to hazardous materials are listed in Introduction: Rascal Resources (Chapter I, Section B(3)) above. Additional information about the training courses can be found in Training: Mandatory Training – Environmental Health and Safety (Chapter III, Section C(5)) in the Sponsored Projects Handbook and in the chapters of the Research Environmental Health and Safety Handbook referred to therein.
9. Radiation Safety

The New York City Department of Health regulations require radiation safety training for all personnel whose work brings them into contact with iodizing radiation or who work in the immediate vicinity of a radiation source and are likely to receive a dose in excess of 10% of the limits specified in the New York City Health Code. Additional information about Radiation Safety training courses can be found in Getting Started: Authorizations and Training: Training (Chapter IV, Section C) in the Research Radiation Safety Handbook.

10. New York State Psychiatric Institute (NYSPI)

If your protocol involves animals housed at NYSPI, please call the Chief Veterinarian at NYSPI at (646) 774-8758 to discuss any additional NYSPI training that is required.

C. Additional Training Resources

1. Training Through the Protocol Preparation Process

The ICM veterinarians and IACUC staff are available to assist investigators in deciding how to use animals in their studies and in preparing the animal use protocols that must be reviewed by the IACUC. Advice can be given on the use of appropriate species, the minimization of the number of animals used and the proper methods of reducing pain, discomfort and distress. This dialogue can be a very effective form of training, since it is conducted on a case-by-case basis when the investigator is most interested in learning appropriate methods for conducting his/her research. See Preparing for a Study: Protocol Preparation (Chapter III) and Preparing for a Study: IACUCApproval (Chapter IV) for additional information on protocol preparation and review.

2. Other Training Upon Request

The ICM veterinarians and the IACUC Compliance and Training Coordinators are available to conduct laboratory specific training upon request. Training topics range from basic techniques to regulatory training, and include ICM wet lab training for rabbits, guinea pigs, dogs and pigs. Skill assessments are also offered for euthanasia and gavage.

For individualized training on a specific procedure with a member of the veterinary staff, complete a Service Request Form, which can be found on the ICM website and submit it online.

D. Occupational Health/Medical Surveillance

In order to protect the health and wellbeing of both humans and research animals, any individual at Columbia or Barnard who has direct contact with laboratory animals, enters an animal facility to perform indirect animal work (i.e., surveys, inspections, etc.) or handles tissues from non-human primates is required to enroll in Columbia’s Occupational Health Program (OHP). See
Occupational Health and Safety (Chapter VII) for information on health and safety issues involved in the use of animals in research. Enrollment in the OHP is mandatory.

The OHP includes baseline hazard identification and risk assessment, as well as an initial medical evaluation and periodic follow up evaluations. Hazard identification covers experimental hazards and hazards intrinsic to animal care and use, with training on occupational health and safety topics such as zoonoses, allergens and special precautions to be taken during pregnancy, illness or immune suppression. Diseases associated with certain animal species are emphasized so that personnel may take appropriate precautions.

The baseline and periodic OHP procedures for investigators and research staff are summarized in the Animal Research Program Worker Grid (Annex II-B).

Faculty, staff and non-Columbia students receive medical surveillance through Workforce Health and Safety (WHS) at CUIMC. WHS is located at CUIMC in the Harkness Pavilion, 1st Floor South (212 305-7590). Animal Research Personnel who require medical clearance to work with laboratory animals may be scheduled for a medical surveillance appointment by their manager. Medical surveillance appointments can be made on-line by completing the medical surveillance registration form at https://secure.cumc.columbia.edu/hrforms/. The form can be accessed by managers through the CUIMC Human Resources website: http://www.cumc.columbia.edu/hr/employment.

Columbia and Barnard students receive medical surveillance through their respective Student Health Services (SHS). An appointment can be set up by contacting SHS at the following numbers:

- Columbia (other than CUIMC): (212) 854-7426
- CUIMC: (212) 305-3400
- Barnard: (212) 854-2091

The following are the relevant SHS locations:

- Morningside campus: John Jay Hall
- CUIMC: 60 Haven Avenue
- Barnard: Brooks Hall Lower Level

A health history form must be completed and signed by each person who works with animals and his/her PI. See Annex II-C for the Health History Form for Students and Personnel with Animal Contact that is used on all Columbia campuses and Barnard.

You should bring the following items to your initial appointment:

- Columbia University ID card
- Completed Health History Form.
- Immunization records, if available.
For personnel working with non-human primates, medical documentation evidencing that
(1) you have been assessed and shown to be free of active tuberculosis in the prior year
and (2) you have had a measles vaccination or measles titers.

For personnel working with sheep and goats, Q fever titers.

The components of the medical surveillance are based on the risks identified in the Health
History Form and may include:

- Medical history
- Two step PPD administration or Quantiferon test, if applicable
- Titers and vaccinations as required by Annex C
- Bloodborne pathogen exposure surveillance
- Biohazard surveillance

Clearance will be granted upon completion of the medical surveillance process. You will not be
charged for the services. Once cleared, WHS or SHS will inform the IACUC via email and the
health clearance date will be entered into Rascal.

At Barnard, the Health History Form must be completed and signed by each applicable staff
member and student and his/her PI. The individual is responsible for contacting the Barnard
Primary Care Health Service to set up an appointment. Once clearance is granted, the Health
Service will notify the IACUC via email. As the Barnard Primary Care Health Service is only
open during the school year, any student who needs clearance during the summer should take the
Health History Form to SHS on the Morningside campus. A letter is then forwarded to the
IACUC by SHS. See http://www.barnard.edu/primarycare for further information.

NYSPI personnel who are working on studies funded through Columbia must also register with
the OHP.

Animal Research Personnel are expected to keep their scheduled appointments and will not be
approved on a protocol if their medical surveillance has not been completed.

If you plan to work with a species that was not covered in your initial medical surveillance or
with infectious agents or materials of human origin, or if a problem arises, you must receive an
additional clearance. In addition, anyone working with non-human primates must receive an
annual clearance.

For questions concerning medical surveillance, please contact:

- For students: SHS on your campus (see phone numbers above)
- For employees: WH&S at CUIMC (see phone number above) or CUIMC Human
  Resources at (212) 305-3127

Any questions or concerns regarding possible exposure to an animal or human pathogen
should be addressed to WHS or SHS, in consultation with the Director of the ICM or

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his/her delegate. See also **Occupational Health and Safety (Chapter VIII)** for a further discussion of occupational health and safety issues.
III. PREPARING FOR A STUDY: PROTOCOL PREPARATION

A. Introduction

IACUC approval of a research protocol for any activity using animals must be obtained before animals may be procured or any work involving animals may be performed. The Columbia University Animal Care Protocol DataSheet (the Protocol) is the key document in obtaining IACUC approval. It describes the objectives, study design, justification for the use of live animals, statistical considerations, personnel qualifications and anesthetic and analgesic procedures. This Chapter will outline the elements of a typical Protocol and provide additional information on several areas of particular concern in animal studies (justification for the number of animals used and alternatives to pain, discomfort or distress).

B. The Three Rs

Columbia is committed to using the fewest animals in research as efficiently and humanely as possible. This approach is called the “3Rs”, which were first described in the Principles of Humane Experimental Technique by Russell and Burch (1959). The 3Rs call for:

- **REDUCING** the number of animals used in experiments to the minimum required to obtain statistically relevant data.
  
  The use of shared control groups, preliminary screening in non-animal systems, innovative statistical analyses or a consultation with a statistician are examples of reduction.

- **REFINING** procedures to minimize pain, discomfort and distress in experimental subjects and provide for their well-being based on their behavioral needs.
  
  The use of analgesics and analgesia, the use of remote telemetry to increase the quality and quantity of data gathered and humane end points for animals are examples of refinement.

- **REPLACING** experiments involving whole animal with *in vitro* models such as tissue and cell culture when possible.
  
  The use of *in vitro*, cell or tissue cultures, models, simulations and use of animal models lower on the phylogenetic scale are examples of replacement.

The 3Rs form the basis for much of the information required in a Protocol and the review of the Protocol by the IACUC.

C. Information Contained in a Protocol

1. Types of Protocols
There are currently four types of Protocols:

- **Research**: Any study designed to generate scientific information relating to a specific area of interest in biomedical and/or behavioral investigations through the utilization of vertebrate animals.
- **Teaching**: Any project that involves instructions about the use of medical devices or surgical techniques or the use of animals to teach biological or psychological concepts.
- **Field Study**: Any study conducted on free-living animals in their natural habitat.
- **Other**: Any other activity that involves the use of vertebrate animals for purposes other than research, teaching or field studies. Examples include animal facility holding and sentinel testing protocols.

2. **Information Contained in a Protocol**

A typical Protocol contains at least the following information, to the extent that it is relevant:

- **Title**: a brief descriptive title of the project being conducted using animals. It is preferable where possible to use the title of the underlying grant that is supporting the work as the title of the protocol.
- **Species**: the common name of the animal being used in the Protocol.
- **Number of animals**: the maximum number of animals that will be used for experimental purposes to accomplish the study objectives for the three years in which the protocol is in effect; for Protocols that include rodent breeding, the investigator must also provide an estimated total of the breeders and offspring for the three years. Lastly, the investigator must provide an estimated total number of animals to be used for personnel training, if any. See *Justification for the Requested Number of Animals (Section 3)* below.
- **Pain and Distress Categorizations**: the category of pain and/or distress applicable to the animals used in the study according to USDA regulations.
  - **Category B**: Animals being bred, conditioned or held for use in teaching, testing, experiments, research or surgery, but not yet used for such purposes.
  - **Category C**: Teaching, tests, experiments or research involving no (or no more than momentary or slight) pain, discomfort or distress or use of pain relieving drugs.
  - **Category D**: Teaching, tests, experiments, research or surgery conducted involving accompanying pain, discomfort or distress to the animals and for which appropriate anesthetic, analgesic or tranquilizing drugs or other methods of relief are used.
  - **Category E**: Teaching, tests, experiments, research or surgery involving accompanying pain, discomfort or distress to the animals and for which the use of an appropriate anesthetic, analgesic or tranquilizing drugs or other methods of relief would adversely affect the procedures, results or interpretation of the teaching, tests, experiments, research or surgery.
• **Funding Source**: the source of funding to Columbia or Barnard (Department, Private Gift, External Government or Non-Government Grant, Government Contract or Commercial Contract). Failure to indicate a funding source can result in the Protocol being returned without review. The funding source needs to be linked with the Protocol for purposes of the comparative review. See *Preparing for a Study: Review and Finalization of Proposals: Approval Process – Additional Approvals and Certifications* (Chapter V, Section C(2)) for further information on comparative reviews.

• **Protocol Personnel**: All personnel with either direct or indirect contact with animals must be listed on the Protocol. Only one person may be identified as the PI. The IACUC needs to know the roles and qualifications of all Protocol personnel and, in particular, the experience each person has with respect to the species to be used and the procedures to be performed under the protocol.

• **Non-ICM housing, satellite, experimental procedure and post-operative locations**: a determination of the various locations of the animals outside of the ICM during various phases of the study. Procedure locations must be visited and approved by the IACUC prior to commencement of the study and semiannually thereafter.

• **Drugs and/or other substances**: a list of the anesthetics, analgesics or other drugs or substances that will be injected, topically applied or otherwise administered to live animals. Note that if a drug regulated by the federal Drug Enforcement Administration (e.g., ketamine, buprenorphine, pentobarbital, etc.) will be administered by laboratory personnel rather than ICM staff, Appendix I must be completed in Rascal and attached to the protocol. In addition, the PI must be in possession of the requisite registration and/or license. See *Animal Care and Use During a Study: Animal Health – Controlled Substances* (Chapter VII, Section E(9)) and *Controlled Substances* (Chapter X) in the *Research Environmental Health and Safety Handbook* for additional information on controlled substances.

• **Hazardous materials**: an indication of the use of recombinant DNA, infectious agents, human or other potentially infectious materials, lasers, hazardous chemicals (e.g., isoflurane, formaldehyde, bromodeoxyuridine, tamoxifen and toxins), radioisotopes or controlled substances in animals. A Protocol will not be approved until the appendix or appendices describing the procedures for safe handling and disposal of hazardous materials have been approved and all research personnel have completed the required training. These appendices can be found in Rascal and are submitted in Rascal with the Protocol. In 2019, a single biological materials Appendix A replaced the three existing appendices for recombinant DNA, infectious agents and human materials or other potentially infectious materials. In addition, approval of the use of isoflurane and/or formaldehyde is now granted for the full duration of the Protocol; the use of other hazardous chemicals will continue to require annual approval. See *Occupational Health and Safety: Use of Hazardous Materials in Animal Research* (Chapter IX, Section E) in the *Research Environmental Health and Safety Handbook*.

• **Objectives of the study**: a brief description of the aims and significance of the study. A statement of the value to society of the research in lay language is required.
• **Justification for use of live vertebrate animals:** an explanation as to why live vertebrate animals are essential to the Protocol, including the options considered as possible alternatives to using live vertebrate animals.

• **Alternatives to pain and distress:** if the procedures could cause more than momentary or slight pain, discomfort or distress, for USDA Animals a written narrative of the methods used to determine whether or not less painful or less stressful alternatives exist to those procedures, as evidenced by a literature search. Each and every procedure that could cause pain, discomfort or distress must be identified and justified, even if anesthetics or other pain or stress relieving agents are administered. Two or more databases must be searched and the identity of the databases, the date of search, the key words used, the years covered by the search and the number of hits obtained must be provided. A brief narrative explaining the search results and the rationale for why the alternatives are not appropriate for the study should be included. A search with zero hits is usually indicative of an inefficient search strategy or an inappropriate database. Conversely, searches that produce hundreds or thousands of hits should be refined to a reasonable number that can be evaluated for their relevance. Inappropriate or inadequate searches are one of the most common reasons for having a Protocol returned. For non-USDA regulated species, a brief discussion of alternatives considered, but not implemented for scientific reasons must be provided.

• **Justification for choice of particular species:** describe the appropriateness of the species chosen.

• **Justification for animal numbers:** a statistical justification of the maximum number of animals to be used is expected. A representative power analysis is recognized as an efficient means of illustrating the group size needed. Include all animal numbers in the justification, including those used for personnel training and breeding and those that will be culled, in addition to experimental animals. See **Justification for the Requested Number of Animals (Section 3)** below.

• **Animal Use Narrative:** a clear, concise, sequential description of the experimental design, procedures, experimental drugs and husbandry from acquisition of the animal until euthanasia. There is a separate section for surgical procedures and surgical details should not be included as part of the study design. The description should include enough detail for a clear understanding of what will happen to each animal. All study groups should be described.

• **Known or expected adverse events:** a description of the known or expected adverse effects of the planned procedures on the animals. Known study endpoints should be defined, together with monitoring plans and interventions.

• **Period of time animals expected to be used:** identification of the period of time the animals are expected to be used from acquisition until euthanasia.

• **Description of unusual conditions:** a description and scientific justification of unusual conditions such as prolonged physical restraint, nutritional distress or abnormal environmental conditions, multiple major survival surgeries and the expected response of the animals.
• **Description of blood collection procedures**: a description of blood collection procedures including method, volume, number of blood draws and, if appropriate, the anesthetic used during the procedure.

• **Non-pharmaceutical grade chemicals**: a description of and justification for the use of non-pharmaceutical grade chemicals.

• **Neuromuscular blocking agents**: a justification for the use of neuromuscular blocking agents, together with the details of anesthesia monitoring.

• **Survival or non-survival surgeries**: a detailed description of the surgical procedures, including anesthetic and analgesic use.

• **Justification for multiple surgeries**: an explanation of the multiple survival surgeries and why they are required.

• **Anesthetic protocol description**: a description of the usage of anesthetic and/or analgesic agents, including anesthesia monitoring.

• **Use of photography or videography**: a description of the techniques used in particular stages of the experiment, and an attestation that the University’s policies and procedures regarding the use of photography and videography in animal studies will be followed.

Additional data may be required depending on the type of research the Protocol covers. If the study involves Pain Categories D and E, the PI must request a veterinary consultation through Rascal. Once completed, the name of the veterinarian who was the consultant and the date of the consultation will automatically be entered in the Protocol.

Samples of the [USDA Animal Care Protocol Datasheet](#) and [Non-USDA Animal Care Protocol Datasheet](#) can be found in Annex III-A and Annex III-B, respectively.

A series of IACUC pre-approved templates for commonly used procedures ([standard procedure descriptions](#)) are available to mouse and rat users in Rascal to assist investigators in preparing Protocols.

### 3. Justification for the Requested Number of Animals

Federal law requires adequate justification for the number of animals used in a study. The PHS Policy states that “the animals selected for a procedure should be…..the minimum number required to obtain valid results.” The Guide provides that “whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis)”. See the Guide, Chapter 2. As a result of these directives, the IACUC requires a statistical analysis whenever possible and reviews the justification for the requested number of animals carefully. A justification based on the rate of use (e.g., the number of experiments performed per week) is typically not acceptable.

The number of animals used for experiments, breeding or personnel training must be listed separately, and a justification must be provided for each use.

**Statistical Protocols**
Any protocol in which a statistical analysis is proposed should include a power analysis to determine an adequate sample size. If you are unfamiliar with power analyses, consult with your departmental biostatistician or member of the Biostatistics Department.

Power analysis requires the investigator to choose an appropriate effect size (or power), and in those cases where it is required, the standard deviation variance for the analysis. You must keep in mind that not all power analyses require a variance estimate (i.e., differences between proportions). At a minimum, a power analysis should:

- Specify the outcome variable(s) and the unit(s) of measurement.
- Specify the statistical test(s) to be employed.
- Specify the desired effect size to be detected in the unit of measurement – not as a percent (percentages and proportions do not always behave as normal distributions unless they are transformed). If a change is to be tested, present the baseline value as well. Do not present the effect size as a calculated “dimensionless” value (i.e., as in Cohen’s “d”) but use the actual measurement units.
- Specify the standard deviation (for continuous data). This value may be obtained from the veterinary literature, other published research, the investigator’s previous research, or if the proposed study is unique, from a small pilot study.
- Specify the Power) levels.
- Provide the calculated sample size(s).

If there are many components to a study (many different tests or analyses), the appropriate way to perform a power analysis to computer one for each procedure. This could be an onerous requirement. It would be acceptable to use the power analysis for the component with the greatest variance (i.e., largest N). If the experiment can be broken into broad categories of data, (e.g., behavioral, biochemical), one analysis per category would be preferable.

Please note that the IACUC does not ordinarily approve justifications for sample size by reference to other “similar” studies in the literature or to previous studies by the investigator. Because it is rarely if ever known how the sample size of other published studies was determined a priori, their use is not appropriate. In cases where the previous study is that of the current investigator, it is relatively simple task to use the variance data from those experiments and calculate a new sample size. The standard deviations from published studies may also serve as an estimate for inclusion in a power analysis.

Non-Statistical Protocols

The IACUC does not require statistical justification for certain protocols relating to the following subjects, but provides guidelines for what alternative information should be provided, as follows:
• **Training**: The investigator should specify the number of procedures to be employed, the number of procedures per animal, the number of animals per student or students per animal, and the number of students to be trained. The total number of training sessions per year and the approximate schedule would be helpful for ICM planning purposes. From these numbers, an appropriate total can be easily calculated.

• **Breeding.** The investigator should provide a chart showing the matings and the yield of each genotype, as well as the total number of the target genotypes produced and the number to be used in experiments with a reference to the approved Protocol(s) in which they will be used. The number should closely relate to the numbers required in the approved Protocol(s) for which the genotype is being developed.

• **Tissue/Cell Collection.** The number of cells required for each phase or the weight of tissue required must be specified. The yield per animal is divided into the requirement to produce a sample size. This too must relate to the Protocol. Throughput or rate of use (e.g., number of animals per week) alone is not sufficient justification. The total weight of tissue/number of cells should refer back to the quantity required by one or more experiment-specific protocols or to answer a specific scientific question.

• **Intracellular Recording.** This is the most difficult case, as there are studies where one animal is used for many recordings or multiple brain slices from one animal are to be used. An unambiguous statement of the number of recording sites needed and the approximate yield per animal is helpful, but cannot always be stated with accuracy. Every effort must be made to state the requirements clearly and as unambiguously as possible so the IACUC can understand the requirements.

4. **Literature Search for Alternatives to Painful/Distressful Procedures**

The 1985 Amendment to the AWA and the resultant 1989 revisions to the AWA Regulations require a PI to consider alternatives to procedures that may cause more than momentary or slight pain or distress to USDA regulated animals, and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions and replacements.

Note: The databases listed below can be used to assist in the provision of the narrative on alternatives to painful or distressful procedures for non-USDA Animals. A literature search is not required for these species, but may be helpful.

**Before you begin your search:**

- Consider other possible animal or non-animal models (e.g., tissue culture, cell culture, fish, rats, etc.).
- Consider your objectives and endpoints.
• Note any drugs or compounds used in procedures (e.g., anesthetics, analgesics, test compounds, etc.).
• Note methods and procedures using animals, paying particular attention to those procedures that may cause pain in or distress to the animal.
• List any potential alternatives (all 3 Rs) of which you are aware (e.g., alternate models, modified techniques, housing modifications, modified restraint, in vitro methods, computer simulations, etc.).
• Develop a conceptual search strategy using the keywords and concepts you noted above. A search strategy is necessarily flexible, dependent both on the topic and on the database selected. If too many records are retrieved, additional relevant terms may make the results fewer and more useful; if too little is retrieved, fewer terms and a more conceptual approach may identify the relevant material. Use these terms and concepts as needed when searching in the databases referred to below.

Performing the search:

• Each and every procedure that could cause pain or distress should be identified and used as an individual search keyword.
• Provide the date that the search was performed.
• Identify the databases. **Note:** Google, Google Scholar and the USDA National Agricultural Library (AGRICOLA) are not considered acceptable.
• State the years included in the search (note that the most recent 10 or more years must be covered).
• Provide the number of hits that were found.
• Briefly describe the search strategy and results of the search and the alternative procedures that were found. State why any less painful or less stressful alternative procedures cannot be used.

Remember that two or more databases must be searched. Failure to address the bulleted points above is one of the most frequent reasons for having a protocol returned for revision.

Databases

The following are suggested online databases that are sources for a literature search. They are divided by the type of study that the Protocol relates to: research, teaching or testing. The librarians at the Augustus C. Long Health Sciences Library in the Hammer Health Sciences Building can also be of assistance. The main reference desk can be reached at (212) 305-3692 or hs-library@columbia.edu.

Research

Recommended database for most users:

• AWIC: Alternatives and the AWA Brochure
Sample searches, methods and guidelines, training and education, databases, organizations and other resources that can assist in understanding alternatives, finding alternatives and completing the alternatives search.

- **Medline**

More specialized databases:

- American Psychological Association – PsycInfo
- Animal Welfare Institute – AWI Lab Animals
- Australian and New Zealand Council for the Care of Animals in Research and Teaching LTD – ANZCAART
- Canadian Council on Animal Care – CCAC
- Defense Technical Information Center – DTIC
- Fish, Fisheries and Aquatic Biodiversity Worldwide – Fish, Fisheries
- Institute for Laboratory Animal Research – ILAR Animal Models
- ISI Web of Knowledge – Web of Science
- Jackson Laboratories – JAX
- John Hopkins Alternatives to Animal Testing - AltWeb
- Model Organisms for Biomedical Research – NIH Model Organisms
- National Cancer Institute – NCI Mouse Models
- National Technical Information Service - NTIS
- Research Portfolio Online Reporting Tools – Online Reporting
- U.S. National Library of Medicine NIH – PubMed (Medline)
- Wildlife Information Network – WildPro Info Network
- The Zebrafish Model Organism Database – ZFIN

**Teaching**

- Citations and Abstracts – CAB
- The Education Resources Information Center – ERIC
- The Norwegian Reference Centre for Laboratory Animal Science & Alternative – Norina

**Testing**

- Alternatives to Skin Irritation and Corrosion Testing in Animals – Rise for Animals
- Bibliography on Alternative to Animal Testing – AltBib
- Ecotoxicology Database – EPA - EcoTox
- European Centre for the Validation of Alternative Medicines – ECVAM
- Interagency Coordinating Committee on the Validation of Alternative Medicine – ICCVAM
- Toxicology Data Network – ToxNet

**Additional Resources**

*Updated November 2020*
AltWeb
- Alternative news, information and resources http://altweb.jhsph.edu

UCDAVIS Center for Animal Alternatives Information
- Assistance with the search for alternatives mwwood@ucdavis.edu
  https://www.library.ucdavis/guide/alternatives

USDA Animal Care Policy Manual
- Policy 11 – Painful Procedures
- Policy 12 – Consideration of Alternatives to Painful/Distressful Procedures

Alternatives Search Tip Sheet – NIH Library
IV. PREPARING FOR A STUDY: IACUC APPROVAL

A. Introduction

All animal research at Columbia must be approved by the IACUC, which focuses primarily on the humane care and use of animals. Once a study is approved, the IACUC approves modifications to the Protocol, conducts annual continuing reviews and postapproval monitoring and, if necessary to protect the welfare of animals, can suspend a project.

There is information about the IACUC, applicable regulations, the review process, etc. on the IACUC website: https://research.columbia.edu/content/institutional-animal-care-and-use-committee

Please note that for studies using animals housed at NYSPI, the IACUC approval process is different than that followed for studies that use animals housed at Columbia. See Steps in Obtaining IACUC Approval – NYSPI (Section B(11)) below for details.

B. Steps in Obtaining IACUC Approval

1. Creation of Protocol

The IACUC process begins with the creation of the Protocol for the study in Rascal. See Preparing for a Study: Protocol Preparation (Chapter III) for a description of the elements of a Protocol. Rascal can be accessed by selecting “Animal Care” and “Create a Protocol,” at https://rascal.columbia.edu/. Information may be entered in fields and documents may be attached electronically. Other required documents (e.g., appendices for hazardous materials, study design tables, etc.) can be attached in the Rascal file and relevant documents that are available only in paper form can be scanned and attached.

The IACUC provides guidance and tools to facilitate protocol submission to the IACUC at https://research.columbia.edu/content/institutional-animal-care-and-use-committee. The IACUC Office also provides a consultation service to assist investigators in preparing new protocols, modifying existing protocols or responding to IACUC review comments. Contact the Office via iacuc@columbia.edu or 212-305-2404.

All actions relating to a specific Protocol, including material submitted, correspondence generated, internal IACUC notes and documents, history and status, are stored together electronically within the Rascal “file” for the study. IACUC staff and members may view all entries and attachments for each Protocol once the Protocol has been submitted, but may not directly modify the submitted material.

2. Submission of Protocol
The Protocol must be submitted to the IACUC through Rascal. Submission requirements and dates can be found at [https://research.columbia.edu/content/protocol-submission-and-review-dates](https://research.columbia.edu/content/protocol-submission-and-review-dates).

Please note that only a PI may submit a protocol to the IACUC. A PI is required to be an Officer of Instruction at Columbia with a full time appointment and the rank of Professor, Associate Professor, Assistant Professor or Instructor. Columbia Senior Research Scientists/Scholars and Research Scientists/Scholars may also serve as PIs. Any other person wishing to act as a PI requires a waiver from the Senior Vice Dean of the Vagelos College of Physicians and Surgeons for studies at CUIMC and the EVPR for studies at the Morningside and Manhattanville campuses. See Preparing a Sponsored Project Proposal: PI Eligibility (Chapter IV, Section C) in the Sponsored Projects Handbook for more information on PI eligibility.

### 3. Protocol Pre-Review

There are two kinds of pre-reviews for Protocols: (a) veterinary consultation or pre-review, and (b) administrative pre-review:

**Veterinary Consultation or Pre-Review**

The AWA Regulations require that procedures that may cause more than momentary or slight pain or distress be formulated in consultation with a veterinarian. The PI may, but is not required to, consult with an ICM veterinarian during the development of a Protocol relating to studies in Pain Categories B and C. Columbia requires a veterinary pre-review for all studies in Pain Categories D and E so that appropriate medications, anesthesia and husbandry are provided for and that errors and omissions in the Protocol are minimized. See Review Process (Section 4) below.

Investigators can request a veterinary consultation directly through Rascal by clicking the “veterinary consultation” button located in the menu listing on the left side of the screen when creating your Protocol (or modification). Once the Protocol is submitted for a veterinary consultation, it will automatically be routed to one of the ICM veterinarians, who will respond within five business days. A pain category D or E level Protocol cannot be submitted to the IACUC for review without first having requested a veterinary consultation through Rascal.

**Administrative Review**

The IACUC Administrative Assistant/Coordinator initially reviews all submitted Protocols. The pre-review of a Protocol is designed to ensure that each Protocol is submitted with the necessary information to proceed with IACUC review and that each Protocol will receive all relevant regulatory considerations.

Once pre-review of a Protocol has been completed, the IACUC administrative staff sorts the Protocols into two groups based on the USDA pain categories:
• Categories B and C
• Categories D and E

At the end of each week, a list of all Protocols that have been received during the week (the Weekly Protocol List) that includes a summary description of each Protocol is provided to each member of the IACUC.

4. Review Process

There are three types of IACUC reviews: (a) by a Designated Reviewer without subcommittee consultation, (b) by a Designated Reviewer with subcommittee consultation or (c) by the full Committee.

Designated Reviewer without Subcommittee Consultation

Unless full Committee review has been requested (see Full Committee below), Protocols in Categories B and C are reviewed by a single member of the IACUC (the Designated Reviewer) selected by the IACUC Chair. The Designated Reviewer’s review must include a consultation with a member of the IACUC staff who is also a member of the IACUC.

Designated Review with Subcommittee Consultation

Unless full Committee review has been requested (see Full Committee below), Protocols in categories D and E are reviewed by a Designated Reviewer selected by the Chair who consults with one of the two subcommittees of the IACUC, each of which includes at least one ICM veterinarian.

Full Committee

Any member of the IACUC may obtain full Committee review of any Protocol by requesting such review (a) for Protocols in Categories B and C, prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List and (b) for Protocols in Categories D and E, at or before the meeting of the subcommittee at which the Protocol will be discussed. Additionally, any IACUC member may call for full Committee review while a Protocol is under review. In any event, IACUC members will have a minimum of two business days to request full Committee review of any Protocol.

Most Protocols involving non-human primates require full Committee review.

If full Committee review is requested, the Committee will meet at a convened meeting at which a quorum is present to review and approve, require modifications in (to secure approval) or withhold approval of a Protocol. Approval or withholding approval of any Protocol for which full Committee review has been requested requires the affirmative vote of a majority of the quorum present at the meeting. If the outcome of the review is to require modifications to secure approval of the Protocol, the Committee will vote either to return the revised Protocol for full
Committee review or to allow a Designated Reviewer appointed by the IACUC Chair to review the revised Protocol. For protocols in Categories B and C, the review by the Designated Reviewer includes consultation with a member of the IACUC staff who is also a member of the IACUC. For protocols in Categories D and E, the review by the Designated Reviewer includes consultation with an ICM Veterinarian. If the Committee votes to allow a Designated Reviewer to review the revised Protocol, it will be placed on the Weekly Protocol List when it is submitted, and all members of the IACUC will have the opportunity to obtain full Committee review of the revised Protocol by requesting such review prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List. In any event, IACUC members will have a minimum of two business days to request full Committee review of the revised Protocol.

**EH&S Review**

Review of Hazardous Materials Appendices takes place concurrently with the Protocol review. Appendix A is with respect to the use of biohazardous materials approved after successful completion of an EH&S conducted Animal Care Survey and review by the University’s Institutional Biosafety Committee (**IBC**). Appendices with respect to the use of other hazardous materials (Appendix D: lasers or Appendix E: hazardous chemicals or toxins) are approved after successful completion of the EH&S Animal Care Survey. EH&S review also includes verification of completion of EH&S training by all personnel listed on the Protocol.

5. **IACUC Meeting Schedule**

Each Protocol review subcommittee meets once a month. Meeting schedules for the IACUC are posted on the IACUC website at [https://research.columbia.edu/content/protocol-submission-and-review-dates](https://research.columbia.edu/content/protocol-submission-and-review-dates).

6. **Protocol Determinations**

Following the Designated Reviewer’s consultation with an IACUC staff member who is also a member of the IACUC (for Protocols in Categories B and C) or with the applicable protocol review subcommittee (for Protocols in Categories D and E), the Designated Reviewer may approve, require modifications in (to secure approval) or request full Committee review of the Protocol. The Designated Reviewer may not decide to withhold approval; that decision may only be made by the full Committee. Protocol approval requires both the approval of the Designated Reviewer and the expiration of the time period provided to all IACUC members to request full Committee review (without any such request having been received) and is effective only after both have occurred.

In addition, final IACUC approval may not be given until evidence of the following has been entered into Rascal:
• Completion of all relevant training courses by the PI and all other personnel listed on the Protocol
• EH&S approval of Hazardous Materials Appendices, if applicable
• Radiation Safety Officer approval of Radiation in Animals Appendix, if applicable

See **Getting Started: Training: Mandatory Training (Chapter II, Section B)** for a more detailed discussion of the foregoing requirements.

The administrative staff of the IACUC notifies each PI in writing of the determination of the Committee with respect to his/her Protocol. When the decision is to withhold approval of a Protocol, or to require modifications to secure approval, the letter contains a statement of the reasons for the decision and the PI may respond to the Committee in writing or in person. The IACUC staff notifies the IO and the Vice President for Research Operations and Policy if the final decision is to withhold approval of a protocol.

### 7. Protocol Modifications

Any proposed change to the Protocol procedures, personnel or procedure locations must be submitted to the IACUC for review and approval prior to implementation.

In order to modify a Protocol, a Columbia University Animal Care Protocol Modification Datasheet (Protocol Modification Datasheet) should be submitted to the IACUC through the modification module in Rascal. A sample Protocol Modification Datasheet can be found in **Annex IV-A**. In the modification module, the type of modification must be selected in the appropriate check box.

If the change is not significant, the modification will be reviewed by the IACUC staff. Such changes include but are not limited to the following:

• A change in funding source
• The addition or deletion of personnel (other than the PI)

All significant changes are approved in accordance with the procedures described in this **Chapter IV** for initial Protocols. Such changes include, **but are not limited to**, the following:

• A change in the PI
• A change in the overall aims or objectives of the study
• A change that may involve an increase in the levels of pain, distress and/or discomfort or degree of invasiveness
• A change from non-surgery to surgery, from minor to major surgery, from non-survival to survival surgery or from single to multiple survival surgery
• An increase greater than 10% in the number of animals required, for Protocols involving the use of frogs, mice, rats or fish
• Any increase in the number of animals required, for Protocols involving species other than frogs, mice, rats and fish
• A change in the genus or species of animals used
• The addition of a use of hazardous agents in animal procedures
• A change in anesthetic agent(s) or the use or withholding of analgesics
• A change in the method of euthanasia
• A change in a location where animals are housed or used, if such location is outside the ICM
• A change that impacts personnel safety.

Protocol deviations (i.e., veterinary discretionary changes that are not in accordance with the approved Protocol, but are approved on an emergency basis by the Attending Veterinarian or his/her designee) that occur during the study should be immediately submitted as modifications, unless the change involves an unanticipated problem involving unintended death of a USDA Animal, which should be submitted using the Adverse Event reporting module in Rascal. See Institutional Monitoring During A Study: IACUC – Adverse Events (Chapter IX, Section C(4)).

8. Continuing Review

Each investigator whose Protocol has previously been approved by the IACUC is required to submit a Protocol Continuation Datasheet to the IACUC prior to each anniversary of the date of such approval. The purpose of the animal Protocol Continuation Datasheet is to enable the IACUC to review the activities under the Protocol on an annual basis. A sample Protocol Continuation Datasheet can be found in Annex IV-B.

Rascal automatically sends a notification that an annual Protocol Continuation Datasheet is required to investigators 60, 45 and 15 days prior to the expiration date of the then current IACUC approval. Investigators are required to submit renewal requests in Rascal. If the renewal includes significant changes, investigators are encouraged to submit renewals 60 days prior to the expiration date of the IACUC approved Protocol, as the Protocol continuation will be reviewed in accordance with the procedures established for review of an initial protocol. Renewals describing minor or no changes should be submitted at least 15 days prior to the approved Protocol expiration date. In any case, submission of a renewal with less than 10 days prior to expiration will not allow sufficient time for Committee review and will result in the expiration of the Protocol.

Upon receipt of a Protocol Continuation Datasheet, the administrative staff of the IACUC includes the Protocol continuation in the Weekly Protocol List provided to each member of the Committee. Copies of the completed Protocol Continuation Datasheets are available to all IACUC members via Rascal. Any member of the IACUC may obtain full Committee review of the proposed continuation of activities by requesting such review prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List. Additionally, any IACUC member may call for full Committee review while a modification or continuation is
under review. In any event, IACUC members will have a minimum of two business days to request full Committee review. Unless full Committee review has been requested or significant changes have been proposed, each Protocol Continuation Datasheet is reviewed by a Designated Reviewer, whose review includes consultation with a member of the IACUC staff who is also an IACUC member (for Pain Categories B and C) or an ICM veterinarian (for Pain Categories D and E). Approval of the continuation of activities under a Protocol is effective only after the expiration of the time period provided to all IACUC members to request full Committee review (without any such request having been received) and the approval of the Designated Reviewer.

Failure to submit a Protocol Continuation Datasheet on a timely basis will result in automatic expiration of the approval of the activities under the Protocol on the anniversary date. In the event of expiration, all experimentation must stop, any animals housed on the expired Protocol must be placed on the ICM Holding Protocol and no new animals may be purchased, imported or transferred on the expired Protocol. The PI will continue to be responsible for all per diem and associated charges during the time that the animals are on the ICM Holding Protocol.

Activities under each Protocol must be reviewed de novo at least once every three years, by submitting a new Protocol (rather than a Protocol Continuation Datasheet). The Protocol is reviewed in accordance with the procedures described in this Chapter IV for initial Protocols. Rascal automatically sends a notification that a new Protocol is required to investigators 60, 45 and 30 days prior to the expiration date of the then current IACUC approval.

9. Voluntary Study Termination

The PI can voluntarily terminate a study at any time. The PI should notify the IACUC Office by email when he/she knows that a study will be terminated.

When an investigator leaves Columbia to go to another institution, he/she is required to consult with the ICM Director to discuss the transfer of animals leaving Columbia and plans for any animals remaining at Columbia. See also Animal Care and Use During a Study: Animal Transfers (Chapter VII, Section F).

10. For Cause Study Suspension or Termination

As further described in Institutional Monitoring During a Study: IACUC (Chapter IX, Section C), if the IACUC has determined to suspend a Protocol, notification of the suspension is sent by the IACUC to the PI and any other responsible individuals, with copies to the IO and the Vice President for Research Operations and Policy, who, in consultation with the IACUC, the Director of the ICM, the Chair of the IACUC and the Executive Director of the IACUC Office (the IACUC Executive Director), will review the reasons for the suspension, take appropriate corrective action and, if required, report the suspension and corrective action to OLAW and the USDA.

11. NYSPI
If animals are housed at NYSPI and are to be used in a study that has funding awarded to Columbia, the IACUC approval process for the Protocol relating to such a study (a NYSPI Protocol) is somewhat different from the process used for animals housed at Columbia. Otherwise, the approval process remains the same. The following describes the principal differences:

**Creation of a Protocol**

You should use the form of protocol required by NYSPI to create a NYSPI protocol; do not use the Columbia Protocol form. You should contact the NYSPI IACUC to obtain the current NYSPI forms.

**Submission of a Protocol**

A NYSPI protocol is submitted through Rascal under “Health Sciences for NYSPI.” This selection will require the entry of demographic and logistical information, followed by the uploading of the NYSPI form of protocol.

If applicable, Hazardous Materials Appendices are also required. These are flagged as relating to a NYSPI Protocol by choosing “Submitted as a Standalone” in the pull-down menu in the General Information section of the Hazardous Materials Appendix. Completed Appendices are submitted electronically to EH&S with a copy of the NYSPI protocol attached. Online guidance is available at [https://research.columbia.edu/new-hazardous-materials-appendix-system-rascal](https://research.columbia.edu/new-hazardous-materials-appendix-system-rascal). A confirmation indicating EH&S approval of the Appendix or Appendices is returned to the NYSPI IACUC office.

**Review Process**

A NYSPI protocol is reviewed first by the Columbia IACUC. When approved by the Columbia IACUC, the NYSPI protocol must be submitted to and approved by the NYSPI IACUC. Columbia provides a letter to the PI and the NYSPI IACUC indicating that approval by the Columbia IACUC has been granted.

The NYSPI IACUC has its own IACUC meeting schedule, which can be obtained from the NYSPI IACUC office.
V. PREPARING FOR A STUDY: REVIEW AND FINALIZATION OF PROPOSALS

A. Introduction

Any sponsored project proposal – whether involving animals or not – must be reviewed by the appropriate University administrative office to ensure that all of the sponsor’s requirements have been met, the proposal complies with all governmental laws and regulations and University policies and the University’s legal interests are protected and its risks minimized. In addition, the project budget must be thoroughly reviewed for accuracy, allowability and completeness.

B. Review Process

The review process for sponsored project proposals is spelled out in detail in Review and Submission of a Sponsored Project Proposal (Chapter VI) in the Sponsored Projects Handbook.

C. Approval Process

Prior to finalization of any sponsored grant application, proposal or contract, the following approvals must be obtained:

1. PI Certification and Departmental and School Approvals

See Review and Submission of a Sponsored Project Proposal: PI Certification and Departmental and School Approvals (Chapter VI, Section D) in the Sponsored Projects Handbook for a description of the University requirements relating to PI certification and departmental and school approvals of any research project.

2. Additional Approvals and Certifications

In addition to the PI and departmental and school approvals referred to above, certain other approvals must be obtained or certifications made prior to commencing any research project. These steps are described in detail in Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications (Chapter VI, Section E) in the Sponsored Projects Handbook. The Special Approvals Summary in Review and Submission of a Sponsored Project Proposal: Additional Approvals and Certifications (Chapter VI, Section E) in the Sponsored Projects Handbook contains a table that provides links to websites where more detailed information can be found.

Comparative Review

Updated November 2020
All projects and grants funded by such agencies as HHS, PHS, NIH and NSF, as well as those funded by certain non-governmental sponsors (such as the March of Dimes or the Juvenile Diabetes Research Foundation) that require adherence to HHS policies, require a comparative review of the IACUC protocol and the grant documentation for congruence. See NIH Grants Policy Statement – Preaward Policies and Considerations (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm), NIH Grants Policy Statement – Part II: Terms and Conditions of NIH Grant Awards (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3_overview_of_terms_and_conditions.htm) and NIH Just-in-Time Procedures (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm#Just-in-).

The comparative review is conducted by one of the IACUC Compliance and Training Coordinators or another authorized reviewer designated by the IACUC Executive Director. The PI is responsible for providing a copy of the grant application to the IACUC for review. Grant applications should typically be submitted indicating that IACUC approval is “Pending.” A comparative review may result in changes to the Protocol that the IACUC must approve, either as part of the initial Protocol review or as a Protocol modification. Once the comparative review has been completed, the IACUC will provide certification of approval to any sponsor that requires it. Please note that only the IACUC may certify completion of a comparative review.

A PI may request a comparative review at any time after a grant application and a related Protocol have been submitted. It is recommended that the comparative review be requested 30-60 days in advance of the release of the list of grant applications that are within a fundable range, if any. For NIH grants, please forward a copy of any “Just in Time” notice or any notice that your grant application has received a score that is potentially within a fundable range to the IACUC at iacuc@columbia.edu immediately upon receipt, together with a copy of the grant application so that the comparative review can be undertaken promptly.

Protocols to be carried out at NYSPI that are funded through Columbia should be submitted to the Columbia IACUC for comparative review.
VI. ANIMAL FACILITIES AND ORDERING AND HOUSING OF ANIMALS

A. Introduction

There are animal facilities at CUIMC, on the Morningside and Manhattanville campuses and at Barnard. Space is often limited and the acquisition and transport of animals is closely regulated. This Chapter provides a very general description of the facilities and outlines the requirements for ordering and housing animals.

B. Facilities

According to the PHS Policy, an “animal facility” is defined broadly as “any and all buildings, rooms, areas, enclosures or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation”.

1. CUIMC

There are five separate animal facilities at CUIMC (collectively, the CUIMC Facility):

- William Black Medical Research Building (BB) and Vagelos College of Physicians and Surgeons Building (VP&S) (collectively, the BB/P&S)
- Hammer Health Sciences Center (Hammer)
- Edward S. Harkness Eye Institute (Eye Institute)
- Russ Berrie Medical Science Pavilion (Russ Berrie)
- Herbert Irving Comprehensive Cancer Center (ICRC)

2. Morningside and Barnard

There are five separate animal facilities located on the Morningside campus and at Barnard (collectively, the Morningside Facility):

- Sherman Fairchild Building
- Schermerhorn Building
- Northwest Corner Building
- Milbank Hall (Barnard)
- Altschul Hall (Barnard)

3. Manhattanville

There is one animal facility in the Jerome L. Greene Science Center (Greene) on the Manhattanville campus (the Manhattanville Facility).
4. Satellite Facilities

A satellite facility is any containment area outside of a core or centrally designated or managed area in which animals are housed for more than 12 hours for species covered under the AWA or for more than 24 hours for all other species. In order to house animals outside of the CUIMC Facility, the Morningside Facility or the Manhattanville Facility, the ICM must approve the HVAC system at the location and the IACUC must inspect and approve the satellite facility. EH&S must also inspect and approve satellite facilities operating at the ABSL-2 Level or higher.

Establishment of a satellite facility is granted only in unusual circumstances and when there is strong scientific justification.

The Guideline for satellite facilities can be found at https://research.columbia.edu/system/files/ICM/Policies/1.C.2.pdf.

5. Core Facilities

CUIMC provides the following specialized core facilities that are available for use by investigators who work with animals. You can sign up to use a core facility through iLab at https://cumc.corefacilities.org.service-center?institution_id=7.

Containment

All facilities can accommodate animals at the ABSL-1 level and each mouse facility is run as a barrier facility. The ICRC has one modular holding and procedure suite that can be used for work with ABSL-2 and ABSL-3 microorganisms. Greene has an ABSL-2 room on SC2.

Surgery

There is a large animal survival surgery core in BB/P&S with seven operating rooms with adjacent scrub and storage areas, as well as animal and instrument surgical prep areas. In addition, there are ICU and step-down recovery suites with an adjacent nurse’s station and office area for monitoring the animals.

There is an additional large animal survival surgery facility in Greene with four operating tables, adjacent scrub and storage areas, animal and surgical prep areas and isolation recovery cubicles.

Radiosurgery

A targeted radiosurgery irradiator for small animals is available in the ICRC.

Diagnostic and Other Services
ICM provides **diagnostic services** to veterinary staff and investigators. See **Animal Care and Use During a Study: Animal Health: Diagnostic Laboratory (Chapter VII, Section E(2))**. In addition, ICM services include **euthanasia,** **necropsy**, and **radiology**. Isoflurane anesthesia machines are available for use in procedure rooms within a barrier facility or in laboratory space in certain buildings on an as needed basis.

**Irradiation**

There is a whole body rodent irradiator located in the ICRC that is managed by the Center for Radiologic Research. There is also an irradiator on the 20th floor of BB that can only be used for certain investigators housing their animals in BB. There is also an irradiator located on the 11th floor of BB that is managed by the Columbia Stem Cell Initiative. There are 4 additional investigator-owned irradiators outside of the ICM available for rodent or culture use.

The Radiation Research Core Facility, located on the 11th Floor of the Vanderbilt Building at CUIMC, and maintained by the Center for Radiological Research, provides a comprehensive irradiation service. The Facility contains six irradiators that together provide the capability to expose small animals, as well as mammalian cells in culture, microorganisms and macromolecules to gamma-rays, x-rays and 254 nm UV light. The Facility can irradiate small animals, whole body or at select anatomical regions through the use of custom-designed lead shielding or CT image-directed, targeted exposure. The operators of the Facility provides users with guidance for safe and efficient sample exposure, as well as consultation related to experimental design.

**Rederivation/Cryopreservation**

The ICM will facilitate rederivation and cryopreservation at offsite contract facilities for investigators. The PI is responsible for payment for these services directly to the vendor.

**Imaging**

The ICM has fluoroscopy and digital radiography capabilities within BB/P&S. CUIMC has MRI, PET, ultrasound, and CT imaging capabilities for large animals.

The Oncology Precision Therapeutics and Imaging Core (OPTIC) is located in the ICRC. OPTIC is a comprehensive small animal imaging facility that includes many modalities of high-resolution imaging equipment, such as the Bruker 9.4T High-Field Magnetic Resonance Imager, the PerkinElmer IVIS Spectrum optical Imaging suite capable of bioluminescent, fluorescent and Cherenkov imaging, the PerkinElmer Quantum FC micro-CT, and the Fujifilm VEVO2100 high-frequency ultra-imaging system. Its personnel are trained in the operation of each imaging modality and small animal handling procedures, as well as analytical software support for quantitative image analysis. In addition to providing interim animal housing for serial imaging studies, OPTIC also offers onsite facilities for surgeries and other needed modalities. See [http://cancer.columbia.edu/research-group/small-animal-imaging](http://cancer.columbia.edu/research-group/small-animal-imaging).
There is a molecule imaging core laboratory with Micro-CT and optical imaging capabilities in BB.

Greene has four MRI scanners and digital radiology and ultrasound capabilities.

**Behavior Facilities**

There are PI-controlled behavioral testing rooms in Hammer, Russ Berrie, BB/P&S and ICRC and additional behavioral testing rooms in Greene managed by the ICM.

The Mouse Neurobehavior Core (MNBC) is a 1,365 square foot behavior testing facility on BB 19 that will be used to phenotype the most promising novel mouse models of central nervous system disorders. Consisting of eight testing rooms, the MNBC is fully equipped to conduct a wide range of behavioral tests, including tests with respect to neonatal development, ultrasonic vocalizations, sensory and motor functions, neurological reflexes, seizure threshold, circadian activity, anxiety- and depression-like behaviors, social behaviors, social communication and complex cognitive functions. The MNBC employs two full-time technicians to conduct experiments, manage mouse colonies and perform data analysis.

6. **Custom Antibodies**

Pocono Farms, Covance Research Products and Cocalico Biologicals have been approved to create custom antibodies from certain species for Columbia investigators.

Outsourcing customized antibody production using animals requires serious regulatory consideration by the ICM and the IACUC. For further information on outsourcing, contact the ICM Office.

**C. Access to Facilities**

1. **Columbia Personnel**

In order to gain access to the ICM facilities, you must (a) obtain medical clearance from WHS or SHS, (b) complete the requisite training, (c) be named on an approved Protocol and (d) obtain the approval of the ICM. See **Getting Started: Training: Mandatory Training (Chapter II, Section B)** and **Occupational Health/Medical Surveillance (Chapter II, Section D)** for a description of the training and occupational health requirements.

To request access to a particular facility, following the appropriate barrier training or facility orientation, the applicable facility supervisor will enter your UNI into Rascal. Once you are listed on an approved Protocol, you should bring, email or fax evidence of such approval to the ICM Office in BB 1810. Once training has been verified in Rascal by the ICM, access will be permitted.
Access will be granted only for the facility or facilities in which your animals are housed.

A **How to Access the Animal Facility** schematic depicting the access requirements is attached as Annex VI-A.

### 2. Non-Columbia Personnel

All non-Columbia visitors must receive ICM approval to obtain access to an animal facility and either receive medical clearance as required by the **Animal Research Program Worker Grid** attached hereto as Annex C or complete and sign the **Personnel with Animal Contact Waiver Form**. A copy of the Waiver Form can be found in Annex VI-B.

Approved visitors may only tour the facility and/or observe procedures. Visitors may not handle any of the animals or perform any procedures on any animal without the prior approval of the IACUC. The PI must include the names, qualifications and activities of all visitors in his/her Protocol, together with a description of the activities that the visitors will perform on animals. Prior to undertaking such activities, visitors must attend any applicable species-specific training courses offered by the ICM.

Please note that in no case may anyone under the age of 18 work with vertebrate animals.

See also the [Columbia University Guidelines for Short-Term Visitors in Research-Related Activities](#) and the [Guideline for Visitors to the ICM Animal Facilities](#) on the ICM website.

### D. Security

All areas of all animal facilities, including specified elevators, are considered areas with restricted access. Access at CUIMC and on the Manhattanville campus requires an encoded identification card. Access on the Morningside campus requires an encoded identification card, an access code and/or a room key. Access at Barnard requires an access code and/or room key. As indicated above, you will only be given access to the areas in which your animals are housed.

It is essential that research animal areas be kept secure. Encoded cards, access codes or keys may not be shared with anyone else. Your identification card is subject to forfeiture if it is used by anyone other than yourself. Individuals with access may not allow unauthorized persons to enter ICM facilities.

### E. Ordering Animals

All animals must be ordered through the ICM Animal Purchasing Office. **Animals may not be ordered directly by any investigator or member of a research staff.** Animals are either (1) purchased through an Approved Vendor or (2) purchased through a non-approved vendor or received (through a collaboration or by gift) from a source other than an Approved Vendor.
A new Protocol or a modification of an existing Protocol for the receiving investigator’s study must be approved by the IACUC before the transfer is made. Please note that a Protocol Modification is required if the acceptance or acquisition of the additional animals will result in the number of animals exceeding the total number of animals permitted under then existing Protocol. If the transfer represents a purchase, the receiving investigator should indicate the account number to be charged.

1. Animals Purchased From an Approved Vendor

An Approved Vendor is an authorized, licensed vendor or selected area within the vendor’s facility that has been certified by the ICM veterinary staff. A list of Approved Vendors can be found on the ICM website under Ordering, Acquiring, Moving Animals. This list is determined and updated by the ICM veterinary staff and provides essential quality control, protects the health of resident animals and ensures that animals are acquired legally. See Procuring Dogs and Cats for Research on the ICM website.

In order to obtain an animal from an Approved Vendor, an Animal Purchase Form must be completed in full and submitted electronically to the ICM Animal Purchasing Office. The Office will not process requisitions without the following: (a) an active IACUC Protocol that authorizes the requested number of animals to be purchased and (b) a proper chartstring for the payment for the animals. The Animal Purchase Form must be submitted by 11:59 p.m. on Wednesday for delivery the following week, pending availability.

2. Animals Purchased from a Non-Approved Vendor or Received from Another Source

In order to import animals that are not purchased from an Approved Vendor, whether or not the animals will be euthanized upon arrival, a Donation/Transfer from Another Facility/Non-Approved Vendor Form must be completed in full and submitted electronically to the ICM Import/Export Coordinator. The Import/Export Coordinator must confirm that the sending vendor or institution has completed the necessary paperwork for exports. The information includes health reports and a facility description. Prior to the order being placed, the ICM veterinary staff will review the necessary documents to maintain biosecurity at Columbia. Please allow 14 days for this review to be completed. The ordering procedure is the same as described in Animals Purchased Through an Approved Vendor (Section 1) above.

F. Animal Arrival and Quarantine

Importation of any animal into Columbia facilities must be pursuant to an IACUC approved Protocol. Because it can take up to two months for a Protocol to be approved, depending on the complexity of the study, if you do not yet have an approved Protocol, but want to order animals,
it is suggested that a “Holding Protocol” be submitted to the IACUC to permit the receipt and quarantine of the animals. A Holding Protocol can be submitted, reviewed and approved in less time.

All incoming animals from approved vendors are shipped directly to the ICM and notification is given to the requesting investigator. Animals are screened upon receipt for signs of infection or other conditions that would preclude acceptance. You will be notified by telephone or email if any problems with your animals are seen upon their arrival. If you would prefer to be notified by email when your order is placed, please indicate this in the comments section on the purchase order form.

Obtaining rodents other than from Approved Vendors can be approved by the ICM upon request. Acquisition of non-rodent species from other than Approved Vendors is permitted only in rare cases.

All rodents not acquired from an Approved Vendor and all non-human primates, regardless of source, will be quarantined prior to arrival at Columbia. Rodents are quarantined at Charles River Labs; non-human primates are quarantined on site, either in BB/P&S or in Greene, or at an ICM-approved vendor. The quarantine period is typically three weeks for rodents and 45-60 days for non-human primates. During the quarantine period, investigators are typically not permitted access to the animals, nor is breeding permitted.

All animals regardless of source should be allowed sufficient time to acclimate after arrival. The ICM recommends that mice that are not quarantined should be observed for at least 48 hours for non-behavioral studies and 96 hours for behavioral studies prior to use in experiments. Other non-rodent animals should be permitted to acclimate at least 48 hours or as determined by the ICM veterinary staff.

You will be notified when your animals are ready to be released from quarantine. All quarantine procedures, as well as any diagnostic tests, will be charged to the appropriate investigator.

**G. Housing of Animals**

1. **Requests for Housing**

All requests for housing should be made by submitting a [Service Request Form](#) to the ICM. Allocation of animal housing at CUIMC is determined by the ICM management in consultation with the CUIMC ICM Senior Faculty Advisory Committee made up of Department Chairs and senior administrators. The ICM allocates space by request and special needs (e.g., ABSL). If there is insufficient space to fill all requests, prioritization of requests is referred to the CUIMC ICM Senior Faculty Advisory Committee.

Allocations of animal housing on the Morningside campus and Barnard are made by the ICM.
All requests for animal housing in Greene should be made to the Director and Chief Executive Officer of the Mortimer B. Zuckerman Mind, Brain, Behavior Institute, who will allocate such housing in consultation with the researchers and ICM management.

Although the ICM will make every effort to accommodate your needs, on campus housing space is limited. Large animals may only be housed in BB/P&S or Greene.

2. Inventory and Billing

Mice, birds, frogs and fish are recorded per cage or tank. All other species are recorded per animal. The ICM staff conducts a physical count of all cages/animals on a weekly basis. Census sheets are collected at the end of the month for billing purposes. The ICM has begun to integrate Radiofrequency Identification (RFID) technology into its census collection. RFID census collection will be conducted multiple times per week. Cage numbers from the census collection, regardless of the method, are used to calculate actual care days that are billed to the PI on a monthly basis.

New animals will be recorded upon receipt and are added to the current inventory. It is the responsibility of the PI to inform the ICM when animals are terminated at the end of a study or added from other than routine orders (e.g., weaning breeding cages).

Investigators receive a monthly invoice for animal per diems (cage maintenance) and any other services rendered by the ICM. Please see Fees on the ICM website for a listing of current per diem fees.

Fees for Diagnostic Laboratory services can be found under Services on the ICM website. A list of fees for other services can be obtained from the ICM Business Office.

3. Animal Identification and Records

Animal Identification

For proper record keeping and to aid in locating animals requiring treatment, all animals must be identified with individual or cage identification in addition to their animal use protocol numbers. All animal cages, pens or tanks have cage cards or tags for identification. The following additional methods of identification may be used for the following species:

- Rodents: see the Guidelines for Individual Identification of Rodents and Mouse Toe Clipping under SOPs and Guidelines on the ICM website
- Rabbits: ear tags or microchips
- Dogs: tattoos or microchips
- Sheep, calves and swine: ear tags
- Non-human primates: tattoos or microchips

**Cage Card Identification**

Upon arrival, all animals are placed in cages or pens that meet federal space requirements. Incoming animals are marked with a green New Arrival cage card for easy identification. This card should be removed once the cage is identified by an ICM cage card. The ICM cage card, containing the following information, is established for each animal and/or cage of group-housed rodents, received into an animal facility:

- PI name
- Approved Protocol number
- Research laboratory account
- Vendor name
- Species
- Strain/stock/breed
- Requisition number
- Gender
- Animal weight (upon request)
- Animal age (upon request)
- Delivery date
- Cage card number

See Annex VI-C-1 for an example of an ICM New Arrival Cage Card, Annex VI-C-2 for an example of an ICM Non-RFID Cage Card and Annex VI-C-3 for an example of an ICM RFID Cage Card.

The ICM will print cage cards for your laboratory with the appropriate information; the cards can be obtained from the applicable facility supervisor. If a card is lost or damaged or requires modification of pertinent information, please request that new cage cards be printed.

**Do not:**

- Cross off and/or change any of the information on the cage card
- Change the Protocol number, investigator, etc., without prior IACUC approval
- Write over required information
- Use any of the colored pre-printed ICM specialty cards for ID purposes.

For RFID converted buildings, researchers must request additional cage cards through the ICM website at [https://cumc.co1.qualtrics.com/jfe/form/SV_0Gl8EB2Deog1ulv](https://cumc.co1.qualtrics.com/jfe/form/SV_0Gl8EB2Deog1ulv).

**Cage Populations**
To conform to federal guidelines and regulations on space requirements per species, the maximum number of rodents that can be maintained per enclosure has been established by the ICM. See Mouse Housing Density Policy or the Rat Housing Density Policy under SOPs and Guidelines on the ICM website. It is essential that cage populations be kept within these specifications at all times, including when the animals are scheduled for euthanasia.

Cages with newborn animals will be marked with an ICM Pups Born Cage Card indicating the date a litter was identified in the cage by ICM (see Annex VI-D for a sample card). Please do not remove this card. When separating the litter, the card may be turned horizontally for future use.

Cages found to be overcrowded will be identified by the ICM staff by dating and adding a colored “Overcrowded” card to the cage and dating and stamping “Overcrowded” on the back of the cage card. The Facility supervisor will send an email to the person designated by the PI to receive notices (the Designated Investigator) notifying him/her of the overcrowding situation. The PI is required to separate animals into additional cages promptly, but in any event by the end of the day following the day that notification is sent. If the animals have not been separated by such time, the ICM will do so and notify the Designated Investigator. A green ICM Separated Cage Card is placed on the cages (see Annex VI-E for a sample card). The PI will be charged a fee for the service and any per diem charges for the additional cage(s).

If a “harem” mating system is employed, pups must be removed from the cage by three weeks (21 days) of age. They can be weaned or moved to a separate cage with their dam, but they must be separated from the sire and other adult females. Multiple litters of the same or various ages are not allowed in one cage. Please consult with an ICM veterinarian if you have any questions.

The PHS recently cited “chronic failure to provide space for animals in accordance with the recommendations of the Guide” as an example of reportable situation in an informational brief issued to IACUCs. Repeated situations of overcrowded cages or any situation of a grossly overcrowded cage will be reported to the IACUC and the applicable Faculty Advisory Committee for further action.

If your experiment requires that cage populations exceed the recommended levels, this must be justified in your Protocol and must be approved by the IACUC prior to implementation.

Biohazardous Materials

Protocols including the use of biohazardous materials (i.e., infectious agents and recombinant DNA) must be approved by the IBC and/or EH&S as well as the IACUC. Issues of risk and the appropriate biocontainment level (i.e., ABSL-1, ABSL-2 or ABSL-3) for the proposed work are assessed by the PI, with the assistance of the IACUC, the ICM and the IBC. Protocol-specific procedures are developed in conjunction with the ICM veterinarians and the Biological Safety Officers in EH&S. Prior to working with hazardous materials, the PI must contact the applicable...
facility supervisor and veterinarian to obtain housing appropriate for the hazards and undergo any particular training requirements.

Rooms designated for biohazardous materials work (ABSL-2 or ABSL-3) are restricted to PIs and their staff and ICM staff. The ICM staff posts a sign incorporating safety information at the entrance of any area in which infectious animals are held or manipulated. Questions regarding the handling of biohazardous materials should be directed to EH&S at biosafety@columbia.edu.

See also the Guideline for Working with Animals Under Animal Biosafety Level (ABSL) 2 or 3 Conditions and Occupational Health and Safety: Working with Hazardous Agents (Chapter VIII, Section C).

**Escaped Animals**

If any rodent escapes from its cage, it will be trapped and euthanized. Any other animal will be returned to its cage or pen.
VII. ANIMAL CARE AND USE DURING A STUDY

A. Introduction

It is extremely important that all members of the research staff be knowledgeable about the care and use of animals during a study. Proper care and use assures compliance with regulations, the research team’s health, the health and well-being of your and other research teams’ animals and the quality of scientific data. The ICM and IACUC personnel share these obligations with the research team, but it is ultimately the responsibility of each individual to obey the rules, regulations, policies and standard operating procedures (SOPs) that apply to laboratory animals.

B. Policies, Guidelines and SOPs

The ICM has prepared or collected a series of Policies, Guidelines and SOPs. The current Policies and Guidelines cover the topics listed below. The SOPs are too numerous to be listed below, but can be found on the ICM website at SOPs and Guidelines.

1. Policies

- Animal Tissue Sharing
- Assumption of Responsibility for Rodent Care
- Authority of Attending Veterinarian
- Major, Minor and Multiple Survival Surgery
- Mouse Housing Density
- Photography, Videography and Media Relations
- Procuring Dogs and Cats for Research
- Rat Housing Density
- Use of Embryonated Chicken Eggs
- Visitors to ICM Animal Facilities

2. Guidelines

- Conducting in vivo Procedures in Animal Housing Rooms
- Decontamination of Manually Cleaned Laboratory Equipment
- Genotyping in Rodents
- Humane Endpoints for Tumor Growth in Rodents
- Individual Identification of Rodents
- Inhalant and Chemical Methods of Euthanasia
- Mouse Toe Clipping
- Oocyte Harvesting in Xenopus
- Physical Methods of Euthanasia

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• Prolonged Physical Restraint
• Regulating Animal Food and Fluid Administration
• Rodent Blood Collection
• Satellite Facility Requirements
• Survival Surgery
• Transportation of Large (non-Rodent) Research Animals
• Transportation of Rodents
• Use of Adjuvants, Stimulants and Ingestion of Irritants
• Use of Cryoanesthesia (Hypothermia) in Altricial Rodents
• Use of Embryonated Chicken Eggs
• Use of Iodine for Zebrafish Embryo Disinfection
• Use of Jackets and Tether Systems in Non-human Primates
• Use of Non-Pharmaceutical Grade Drugs/Chemicals/Compounds in Research Animals
• Use of Rodent Post-Operative Card
• Use of Tricaine Methanesulfonate (MS-222) in Aquatic Animals
• Working with Animals under Animal Biosafety Level (ABSL) 2 or 3

Please refer to these Policies, Guidelines, SOPs and certain NIH Guidelines under SOPs and Guidelines on the ICM website for important information on the care and use of animals.

C. Biosecurity

Because of the risk of disease to the animals and to the research staff, maintaining the cleanliness of the animal facilities is one of the ICM’s primary responsibilities. However, it is important for each investigator and each other member of the research staff to observe the ICM rules on facility and personal biosecurity precautions.

1. Barrier

All of Columbia’s rodent facilities (except for the area that houses rat colonies located in the Eye Institute and post-procedural housing areas located in the Eye Institute, BB, Greene and Fairchild) are barrier facilities in that measures are taken to prevent the introduction of pathogens.

Please note that once a person enters a non-barrier area (i.e., a conventional facility or necropsy) from a barrier area, there is a mandatory 24-hour waiting period before he/she may re-enter a barrier facility. Therefore, you should always enter the barrier first.

Rodents that leave the barrier facility may not be returned to the barrier under any circumstances. Please note that no rodent may be kept in a laboratory more than 24 hours without explicit IACUC approval. If the animal is unable to be returned to the barrier, it must be kept in the post-procedural housing areas in the Eye Institute, BB, Greene, Schermerhorn or Fairchild.
Personal Protective Equipment must be worn within all barrier facilities.

2. Personal Protective Equipment

The ICM requirements for Personal Protective Equipment (PPE) while working with animals in barrier facilities are as follows:

- Long pants and closed toed shoes must be worn.
- Disposable gowns or long sleeves must be donned upon entering an animal facility in the room or area designated for such. In some areas, a bonnet is also required.
- Gloves are required and should be worn at all times when handling animals.
- Face masks are available, but are optional for all animals other than non-human primates.
- All disposable clothing should be discarded in the receptacles provided upon exiting the facility.

Additional PPE, such as eye protection or an additional pair of disposable gloves, may be required when entering an ABSL-2 or ABSL-3 area or if you are working with biological or chemical hazardous materials or macaques. Requirements for additional PPE are posted at critical entry points to applicable areas of the facility.

3. Sanitation and Waste Disposal

Animal Room and Cage Sanitation

The ICM husbandry staff performs routine, scheduled animal husbandry and sanitation procedures daily, including weekends and holidays. These include bedding changes, sanitization of cages, cage racks and floor pens and cleaning and disinfection of floors, walls, ceilings, ducts/pipes and fixtures in each facility. The ICM maintains a written schedule for these procedures.

Investigators are responsible for cleaning up spills and maintaining clean work areas. Disinfectants are available in most animal rooms, as are disposable gloves, soap, paper towels, brooms, mops and sharps containers for syringe and needle disposal.

Do not leave dirty cages or empty water bottles in the animal rooms. Any equipment borrowed from the ICM should be left in the designated areas for sanitization. Do not leave needles, syringes, test tubes, etc. in the animal rooms. Needles, syringes and scalpels should be placed in appropriate sharps containers. Do not recap needles for any reason. Do not dispose of any sharp objects or glassware in the regular waste.

Waste Disposal

The ICM husbandry staff places soiled bedding and refuse in plastic bags and removes the bags.
The ICM husbandry staff places animal carcasses in plastic bags that are refrigerated until they are shipped out for incineration. Refrigerators are located in each facility and there is a cooler on the 18th floor of BB/P&S and carcass freezers on the SC2 level of Greene.

Infectious agent- and chemical carcinogen-containing carcasses and waste are placed in biohazard containers and removed for disposal by the ICM or the research staff as designated in the relevant Protocol and/or Appendix. Bedding and waste contaminated with chemical hazards may require special handling, e.g., collection as hazardous waste through the EH&S Hazardous Waste Program.

Radioactive waste is stored in containers supplied by Radiation Safety Program personnel and monitored and cleared by such personnel. Radioactive carcasses must be stored in freezers approved by Radiation Safety Program personnel until they are cleared for disposal.

### 4. Vermin Control

The control of vermin (insects and feral rodents) is essential for the maintenance of the health of animals and personnel and proper conditions for scientific research. Columbia Facilities personnel and an outside exterminator are responsible for physical means of control (sealing cracks, humane traps and the use of non-toxic insecticides). Roach bait stations are used in animal rooms and support areas. Pesticides are not used in animal rooms. You can assist in rodent control by maintaining high standards of cleanliness while you are in any of the animal facilities.

### D. Personal Conduct in Animal Rooms

Eating, drinking, smoking and the application of cosmetics in animal rooms or laboratories are prohibited. Please observe all posted notices. Noise should be kept to a minimum and animals handled gently and in a professional manner at all times.

### E. Animal Health

#### 1. ICM Services

The ICM staff is available to aid investigators in their research by providing assistance in special diets, following experimental fast/no fast or water/no water regimens, euthanasia and preserving carcasses and tissues. The veterinary and other trained staff can provide a variety of technical services such as:

- Administration of Medicines
- Anesthesia
- Animal immunizations
- Blood collection
- Pathology (see Diagnostic Laboratory (Section 2) below)
- Purchase of drugs and surgical supplies
- Surgical assistance and post-operative care
- Tattoos
- Tissue/specimen collection

To request these services, please submit a Service Request Form detailing all services and supplies that are requested at least two business days in advance.

It is the expectation that all animals housed within the animal facilities under the jurisdiction of the ICM will be maintained by the ICM staff in accordance with ICM SOPs. The specific needs of some research programs may require deviations from such procedures. For rodents, special services may be provided by the ICM or in certain circumstances rodent care services may be provided by the PI and/or his/her research staff. In the latter case, an exemption must be granted to a PI and approved by the IACUC.

A PI and/or his/her research staff may assume responsibility for the following types of rodent care services:

- Cage changing by PI and/or PI research staff only
- Special diet
- Special water
- Food restriction or deprivation
- Water restriction or deprivation

Please review the ICM Policy: Assumption of Responsibility for Rodent Care Services (the Assumption of Care Policy) for information about the responsibilities of the PI and his/her research staff with respect to managing rodent services. The animal husbandry personnel will still be responsible for observing and monitoring the health and condition of the animals on a daily basis. See Daily Health Evaluation; Sick Animals (Section 4) below.

In order to assume responsibility for rodent care services, once IACUC approval has been granted, you should complete the section of a Service Request Form entitled “Services to be Assumed by the PI and/or His/Her Research Staff” and submit it online. Requests must be made at least 48 hours in advance of the services to be provided. Following ICM veterinary approval of the Service Request Form, the PI must complete and place a blue ICM Service Requisition Cage Card (a Blue Card) on each applicable cage (see Annex VII-A for a sample card). Please note that if the Blue Card indicates food or water restriction/deprivation, the PI and/or his/her research staff must note on the back of the Blue Card the date and time of each provision of service in accordance with the Assumption of Care Policy.

2. Diagnostic Laboratory
The ICM provides a complete range of diagnostic services, including clinical chemistry panels, complete blood count, serum chemistries, parasitology examinations, microbiology testing, coagulation profiles and research services related to molecular biology. The ICM maintains collaborative research relationships with several national and international biomedical research centers and can outsource services if they are not done at Columbia. All histopathology services are outsourced.

See the ICM website for more detailed information and forms for ordering services.

3. Sentinel Program

The ICM maintains continuous health surveillance of rodent colonies through the sentinel program. Sentinel animals are placed in each rack in each rodent room. The animals are housed in individual cages indicated by special cage cards and/or labeling. Do not displace a sentinel cage under any circumstances. Barrier and conventional facilities are tested quarterly. These animals are removed, bled for viral serology, euthanized and necropsied. The test results are posted on the ICM website under Facility Health Reports. In the event of an outbreak, each affected PI will be notified and directed as to which procedures must be followed to contain the pathogen. Health-screening records are maintained by the ICM veterinary staff.

4. Daily Health Evaluation; Sick Animals

The ICM maintains a daily health monitoring program for all research animals. Animal husbandry or technical staff check for sick or injured animals daily. Technicians are trained to identify abnormalities and report them to the veterinary technical staff. The PI’s or research staff’s responsibilities for monitoring animals used in their studies are determined by the Protocol for the study.

Small animals that are observed to be abnormal are identified with an orange ICM Sick Animal Cage Card (Husbandry), the health status report (husbandry section) is completed and a sick animal flag is left outside the door of the room to notify the veterinary technician. See Annex VII-B-1 for a sample card. A sick animal flag indicates there is a new sick animal in that particular room. A designated veterinary technician responds to all sick animal reports on a daily basis. The veterinary technician assesses the animals and if the animal is sick, he/she completes a triplicate carbon copy of a pink ICM Sick Animal Cage Card (Veterinary Technician) that includes date, PI, protocol, room, rack ID, shelf row, clinical signs/diagnosis, initials, recommended plan and follow-up on the cage. See Annex VII-B-2 for a sample card. One copy of the sick animal card remains on the cage, another is left in the holding room for the designated husbandry technician and the third is placed in a binder for use during subsequent rounds, communication with the PI and follow-up treatment. The veterinary technician initials and dates the health status report left in the holding room.

The veterinary technician completes an Animal Health Report and communicates with the PI or laboratory staff via an e-mail for each sick animal detailing the problem and recommended
treatment plan. A **Service Request Form** should be submitted to the ICM to request treatment, indicating the recommended treatment plan (e.g., topical antibiotic three times weekly, Baytril (0.1 mg/ml water in water bottle, changed weekly), euthanasia, etc.). The veterinarian assigned to each facility is copied on all sick animal notification e-mails. All sick animal cards are filed in the veterinary technician office. When animals are found to be in distress or the PI or his/her staff is unavailable, animals are treated by the ICM veterinary staff. If the husbandry staff finds a dead mouse or rat in a cage, he/she places an **ICM Mortality Cage Card** on the cage and gives a duplicate copy to the facility supervisor (see Annex VII-C for a sample card).

A veterinarian or veterinary technician is verbally notified if a clinical problem is identified in a large animal. A clinical record is initiated and the PI is contacted. If the PI cannot be reached within a reasonable period of time, the veterinary staff takes appropriate action.

### 5. Weekends, Holidays and Emergencies

On weekends or holidays, the ICM has veterinary technicians, animal husbandry technicians and an animal husbandry supervisor on site part time (and full time as needed) and otherwise on call. A veterinarian is on site as needed or otherwise on call and available 24/7.

The ICM has established a single phone number to call in order to reach the veterinarian on call. **If you have an animal related emergency after hours or on a weekend or holiday and require immediate assistance, call (917) 232-5319 to speak with a veterinarian.**

At CUIMC, Public Safety Officers patrol the vivaria during working and non-working hours 24/7 and maintain security cameras located throughout the facilities for investigative purposes. On the Morningside and Manhattanville campuses, Public Safety Officers patrol the corridors in the buildings in which the vivaria are located. In both locations, Public Safety maintains contact information for the ICM staff and can contact veterinarians, supervisors or the ICM Director 24/7, as necessary.

**If you have a facility emergency, call Public Safety at CUIMC at (212) 305-7979 or on the Morningside and Manhattanville campuses at (212) 854-5555.**

### 6. Animal Health Records

All animal health records are subject to federal, state and institutional inspections and must be available at all times.

Investigators and other members of a research staff, as well as ICM personnel, are responsible for maintaining accurate and current animal records. Details concerning experimental procedures, anesthesia monitoring, diagnostic tests, post-operative monitoring and any other procedures conducted on an animal must be entered into the record by the person performing the procedure as the procedure was performed. These records should include the drug/chemical agent administered, the total dose received by the animal, the time that the drug/agent was
administered, the route by which it was administered and the signature of the person administering the drug/agent.

Please note that records for all species must be kept and be available for inspection. This is critical for procedures conducted outside of the ICM that may require analgesics, especially survival surgery procedures, indicating that the animals were evaluated for pain or distress and treated accordingly.

The IACUC and ICM have instituted procedures for recording animal health status that will assist you in monitoring rats, mice, gerbils and hamsters post-operatively. See Monitoring Rodents Post-Operatively on the ICM website.

7. Pain and Distress

An important component of the humane care and use of laboratory animals is the prevention or alleviation of pain associated with procedures. A guiding principle is that any procedure that elicits pain in humans will also be painful to animals. Because of this, the proper use of anesthetics and analgesics is an ethical and scientific imperative.

The ICM has developed a number of Guidelines specifically relating to pain and distress such as tumor models, cryoanesthesia (hypothermia), anesthesia monitoring and rodent survival surgery and postoperative care that are available on the ICM website. See Policies, Guidelines and SOPs (Section B) above. Postoperative analgesia is required for all animals and may not be withheld without the express approval of the IACUC. Specific monitoring criteria and humane endpoints are required for all protocols.

8. Animal Surgery

Survival Surgery

The surgical suites in BB/P&S and Greene are available to provide an appropriately maintained facility for large and small animal survival surgeries.

All non-rodent mammalian survival surgeries are done within the ICM. Before approval of a Protocol, investigators must meet with an ICM veterinarian to discuss appropriate anesthetics, analgesics and overall perioperative management.

After the Protocol receives IACUC approval and before the initial procedure, the ICM veterinarian creates a summary of the anesthesia, analgesia and perioperative considerations for the procedure. For complex Protocols, the investigator must meet with the ICM staff to discuss particulars of the project. This allows the ICM technicians to become familiar with the experimental design, discuss any special anesthetic and intraoperative monitoring requirements, special equipment required and postoperative care needs. The general goal of the meeting is to understand better and improve the overall outcome of the experimental project.
Rodent survival surgery can be performed in designated procedure rooms within each animal facility or in a research laboratory, provided that the site is approved by the IACUC. **Note: you must have completed the Rodent Wet Lab Training and Rodent Surgery Training described in Getting Started: Training – Mandatory Training – Rodent Wet Lab Training and Rodent Surgery Training (Chapter II, Sections B(4) and (5)) before your Protocol is approved.** See also the Rodent Survival Anesthesia Monitoring Sheet and Non-survival Anesthesia Monitoring Sheet that are available on the ICM website. The Guidelines include a helpful standardized anesthetic monitoring record and table.

It is very important that for any survival surgery, appropriate aseptic technique and instruments and appropriate anesthesia and analgesia are used. Aseptic technique, regardless of the species, includes preparation of the animal, disinfection of the operative site, preparation of the surgeon (e.g., surgical attire, face mask, sterile surgical gloves), sterilization of instruments, supplies and implanted materials and the use of operative techniques to reduce the likelihood of infection. If you are uncertain as to the appropriate procedures to be used, contact a member of the ICM veterinary staff for instructions.

See also [https://research.columbia.edu/system/files/ICM/Policies/5.1.5.pdf](https://research.columbia.edu/system/files/ICM/Policies/5.1.5.pdf) on the ICM website for further information.

**Postoperative Care**

A key goal of veterinary medical care is the prevention or alleviation of pain associated with procedural and surgical protocols. This is accomplished by the observation of the animal and intervention with analgesics as required.

Animals that undergo surgery in the ICM surgical suite are admitted to the ICU for immediate postoperative recovery. An ICM veterinary technician remains with the animal until the animal is extubated and has recovered from anesthesia. The animals are monitored in accordance with the approved Protocol and are checked by ICM veterinary technicians and an ICM veterinarian on a daily basis. Animals in the ICU are checked multiple times a day as required by the approved Protocol or deemed necessary by a veterinarian. Health rounds are performed in the ICU twice daily and the animal’s condition and related observations and treatments are entered into the animal’s health record.

If survival surgery is performed outside the ICM facilities, it is the responsibility of the investigative staff to provide postoperative care. It is imperative that appropriate analgesics be administered following surgery. There are no exceptions to this directive.

**Remember:**
- Use only pharmaceutical grade drugs. The use of non-pharmaceutical grade compounds must be specifically identified in the Protocol and approved by the IACUC.
Do not use any expired drugs.
Dispose of all expired drugs.
Controlled substances require disposal through a reverse distributor.

If you need assistance in determining which analgesics to use, please contact the ICM veterinary staff prior to surgery.

As indicated in Pain and Distress (Section 7) above, the ICM has developed a postoperative rodent monitoring form which should be used. See Policies, Guidelines and SOPs (Section B) above. The form includes monitoring criteria and analgesia recommendations. Investigators are responsible for maintaining accurate records of anesthetic and analgesic use.

In addition, the ICM encourages the use of an ICM Postoperative Cage Card, a sample of which is attached as Annex VII-D, to help researchers monitor rodents postoperatively and to indicate to ICM personnel the postoperative care that is being given the animals by the researchers.

Non-survival Surgery

Non-survival surgery is defined as a procedure in which the animal is euthanized prior to recovery from anesthesia. Non-survival surgeries may be performed outside the ICM provided that the location of the surgery and the procedures to be used are identified in the applicable Protocol and approved by the IACUC. According to the Guide, it might not be necessary in non-survival surgery to follow all of the aseptic techniques used in survival surgery; however, at a minimum, the surgical site should be clipped, the surgeon should wear gloves and the instruments and surrounding area should be clean. See the Guide, Chapter 4, Surgical Procedures.

9. Controlled Substances

The use of controlled substances is regulated by both federal and state law. In addition, the University has adopted the Columbia University Policy for the Acquisition, Use and Disposal of Controlled Substances in Research (the Controlled Substances Policy). A “controlled substance” is a drug or other substance, or immediate precursor, listed in any of Schedules I–V of the federal Controlled Substances Act (21 USC 801-971) or the New York State Controlled Substances Act (NY Public Health Law, Article 33).

Detailed information on Controlled Substances can be found in Controlled Substances (Chapter X) in the Research Environmental Health and Safety Handbook.

10. Euthanasia

Euthanasia is the act of humanely killing animals by methods that induce rapid unconsciousness and death without pain or distress. All euthanasia procedures must be accepted methods as
outlined in the most current (2013) AVMA Guidelines for Euthanasia that can be found on the ICM website. These include carbon dioxide inhalation, injection of pentobarbital (100mg/kg IP), cervical dislocation (mice and rats weighing less than 200g; anesthesia required) and decapitation (anesthesia required).

You must be trained in the proper methods of euthanasia before euthanizing any animal.

It is advisable that the ICM staff euthanize animals for you. Animals may be left in their original housing room to be euthanized by the staff. A pink ICM Euthanasia Cage Card signed by the PI or a member of his/her research team must be placed on each cage that is to be euthanized (see Annex VII-E for a sample card).

Please note that animals scheduled for euthanasia must be kept in cages holding no more than the number of animals permitted under ICM policies and given adequate food and water. All pups must be kept with the dam. See Animal Facilities, Ordering and Housing: Housing of Animals – Animal Identification and Records (Chapter VI, Section G(3)).

For additional information see the following Guidelines on the ICM website:

- Inhalant and Chemical Methods of Euthanasia
- Physical Methods of Euthanasia

11. Photography and Videography

Although the University recognizes the need for its investigators to include photographic documentation in their reporting of research results, significant care is needed in producing and presenting these images, whether in still photos, video or any kind of imaging method.

Images of animals in laboratories or procedure areas may only be taken only for the purposes of publishing research results in scientific publications, reporting at professional meetings or making presentations at seminars or education or training sessions. Imaging should be limited to only the most essential aspects of the project. Images should not be shared with anyone who is not a member of the research team unless explicitly approved by the PI, the Director of the ICM and the Chief Communications Officer for CUIMC or the Executive Vice President of Communications and Public Affairs for the Morningside and Manhattanville campuses.

No digital, still, video or film camera, or other photographic recording devices are allowed in any location where animals are housed or used without advance written approval of the PI and, if the area is under the jurisdiction of the ICM, the Director of the ICM. Cell phones or any other multi-purpose devices with digital imaging or video capabilities may not be used for photography, video or any other kind of recording at any time in any location.
The complete Policy and Procedures can be found at Policies and Procedures for Photography, Videography and Media Relations Involving Animal-Based Research at Columbia University under SOPs and Guidelines on the ICM Website

F. Animal Transfers

1. Transfer of Animals Within or Between Columbia Facilities

In order to move animals between rooms in the same facility or between facilities at Columbia, the PI must submit an Animal Transfer Request Form online and mark each cage that is intended to be moved by a yellow ICM Animal Transfer Cage Card (see Annex VII-F for a sample card). Once the ICM receives the transfer request, the current health status of the animals to be moved will be reviewed and additional testing may be performed to confirm clear health status. If all health tests are negative, the animals can be cleared for transfer.

If you are permitted to do so by the IACUC and the ICM, investigators may move rodents within or between buildings in accordance with the Guideline for Transportation of Rodents. You may also ask the ICM to move your animals. All other animals are moved by ICM personnel. Do not move animals yourself. The applicable PI or laboratory contact will receive an automated “completed” email when the animals have been moved. Transfers may take 1-2 weeks due to health testing, etc. See the Guideline for Transportation of Large (Non-Rodent) Research Animals on the ICM website for further information.

If you wish to have the ICM move your animals, submit a Service Request Form via the ICM website at least two business days in advance of the proposed move.

Please note that particular procedures will be followed when animals are being moved for irradiation.

2. Transfer of Animals Between Columbia Investigators

The transfer of animals from one Columbia IACUC-approved Protocol to another is done using the Animal Transfer Form on the ICM website. If the transfer involves moving animals within a Columbia facility or between Columbia facilities, the process outlined in Transfer of Animals Within or Between Columbia Facilities (Section 1) above will be followed. Either the donor or the recipient investigator authorizes the transfer by completing, signing and dating the Animal Transfer Form. The Form must include all information regarding the donation or sale and transfer of animals to another investigator. The responsible facility supervisor makes the appropriate changes to the census sheets and generates replacement cage cards indicating the required changes for identification purposes. The ICM usually transfers the animals based on the requested transfer date indicated on the Animal Transfer Form following approval from the receiving building veterinarian. Once the transfer has been made, the building supervisor will
electronically check off “complete” on the Transfer Form and a transfer completion email is automatically sent to all participating parties.

3. **Exportation of Animals**

If a rodent is to be sent to an outside facility, the PI must submit a Rodent Animal Exportation Form/Health Report Request. The ICM will forward the health report to the receiving institution’s veterinarian and will so notify the PI. This may take up to five business days. The ICM will notify the PI of the recipient’s decision to accept the shipment, request additional testing or deny the shipment. Additional testing, if any, will be conducted by the ICM.

A modification of the Protocol for the transferring investigator’s study must be approved by the IACUC before the transfer is made. If the transfer is a sale, the transferring investigator should indicate the account number to be credited.

The PI must separate the animals as outlined below:

- Males and females must be separated.
- Females greater than 14 days of gestation or with litters less than 10 days of age will not be shipped, unless authorized by the receiving institution.

All cages to be shipped should be labeled with the yellow Transfer Card.

If the PI is packing and shipping the animals, he/she should submit a Service Request to order the necessary packing supplies. Please allow seven days for the service request to be completed. The ICM will also pack and ship animals for investigators. Packing and shipping charges will be billed to the PI’s account. If the ICM is handling the shipping, it will track the shipment and notify the PI of the animal’s safe arrival at the recipient institution.

4. **Importation of Animals**

See Animal Facilities and Ordering and Housing of Animals: Ordering Animals and Animal Arrival and Quarantine (Chapter VI, Sections E and F).
A. Introduction

The health and safety of all personnel working with animals is of the utmost concern to the University. Safety is the joint responsibility of the ICM, IACUC, EH&S and each individual working with animals. Research with laboratory animals involves risks that must be recognized. These include the animals, animal waste, concurrent infections, use of hazardous materials and the use of sharp objects. This Chapter provides basic information on health and safety issues involved in the use of animals in research.

If you are unsure of your ability to handle animals or conduct procedures in a safe manner, you should contact the ICM which can provide training and technical assistance.

B. Risks

1. Allergies

Allergies are the most common cause of human disease related to the use of animals in research. Animal allergies can result from exposure through skin contact or inhalation of allergens from fur, dander, saliva, urine, serum or other body products or exposure to contaminated equipment or bedding. Typical symptoms are sneezing, tearing, watery nasal discharge, congestion, skin rashes and asthma.

Prevention can best be achieved through use of engineering controls, work practices, including personal hygiene and use of PPE and other barrier protections. Thorough hand washing after handling animals can prevent skin reactions. Use of a surgical mask is designed to protect the sterile field and work area from droplets generated by the wearer, but is unlikely to prevent inhalation of allergenic particles.

If you experience any symptoms, report them to a facility supervisor, the PI or WHS/SHS.

2. Zoonoses

Although humans are not ordinarily affected by animal diseases, animal species can carry pathogens that are infectious to humans by airborne transmission, direct contact, bites and scratches. PPE such as disposable gowns, gloves and masks should be worn.

The number of potential infections transmissible between animals and man is great; a few examples follow:

Non-Human Primates
Non-human primate diseases can be transmitted to humans and vice versa. Airborne transmission of TB and measles between humans and primates can occur. Monkey B virus (*Macacine herpes virus*), carried by rhesus, cynomolgus and other macaque monkeys, can cause fatal encephalitis in humans, and wounds from these species or contact with any wound or sore contaminated with their body fluids require immediate medical attention. Because of the uncertainty of our ability to determine the viral status in monkeys, you should consider that all monkeys of these species may carry the virus. Infections such as *Shigella*, *Campylobacter*, *Salmonella* and *Entamoeba histolytica* may occur in primate species, so precautions must be taken to prevent transmission. Protective measures such as disposable gowns, bonnets, gloves, shoe covers, face masks and face shields must be used when working with primates. To reduce the likelihood of needle sticks and lacerations, use of engineered sharps injury protection (“safe needles”) is required when working with non-human primates.

**Dogs and Cats**

Bite wound infections and cat scratches can cause fever, lymphadenopathy and cellulitis. Personnel working with dogs and cats must either be vaccinated against rabies or sign a waiver indicating that they decline vaccination. Women of child bearing age without immunity to toxoplasmosis should avoid cat contact to prevent congenital toxoplasmosis and fetal death. Parasites and fungal infections are also possible risks.

**Rodents**

Contact with mice, rats, guinea pigs, hamsters and gerbils requires precautions against *Salmonella*, fungal infections and lymphocytic choriomeningitis virus (from transplantable tumors). Tetanus vaccinations are offered and strongly recommended.

**Other Species**

Tularemia in rabbits, Q fever in sheep, erysipelas in swine and *Chlamydia* and avian TB in birds can cause serious infectious diseases.

### 3. Bites and Scratches

If you have been bitten or scratched by an animal or cut or scratched with an instrument that has been exposed to an animal or its body fluids, you should scrub the wound thoroughly with soapy water, report the incident to the facility supervisor and seek medical attention immediately at WHS or SHS. Evaluation and treatment outside of normal working hours is provided in the emergency room at NewYork-Presbyterian Hospital for personnel at CUIMC and the Manhattanville campus and Mt. Sinai-St. Luke’s Hospital for personnel on the Morningside campus. If you are at CUIMC you should complete a **Departmental Accident Form** (see Annex VIII-A-1 for a sample) and on the Morningside and Manhattanville campuses, an **Animal Handlers Illness/Accident Form** (see Annex VIII-A-2 for a sample) should be completed.
Complications from bite wounds include tenosynovitis, septic arthritis, osteomyelitis, abscesses and fatal sepsis. Symptoms can include fever, inflammation at the wound site, lymphadenopathy, headache, malaise or rash.

C. Working with Hazardous Agents

The use of recombinant DNA, infectious materials, human source material, radioactive materials, hazardous chemicals or controlled substances must be described in a Hazardous Materials Appendix that is attached to an IACUC Protocol. Protocol approval is contingent upon EH&S and/or Radiation Safety Program personnel approving the Appendix. See Occupational Health and Safety: Use of Hazardous Materials in Animal Research (Chapter X, Section E) in the Research Environmental Health and Safety Handbook.

Training is a necessary component of understanding protection against hazardous agent exposure. Training at Columbia is provided in the mandatory courses and training given by the IACUC, the ICM and EH&S. Members of the research staff are evaluated for competence in procedures mandated or recommended in EH&S policies and procedures. EH&S provides generic training based on hazard class. Training on specific hazards is the responsibility of the PI. You must also alert others who may be inadvertently exposed to agents. Any staff member exposed to hazardous materials or with suspected exposure should contact WHS or SHS as soon as possible. See Getting Started: Training: Mandatory Training – Environmental Health and Safety (Chapter II, Section B(8)) above.

EH&S maintains up-to-date guidance for the use of hazardous materials in research laboratories. See the EH&S website http://www.ehs.columbia.edu/ for further information.
IX. INSTITUTIONAL MONITORING DURING A STUDY

A. Introduction

As mandated by federal regulations, Columbia has the clear and unmitigated obligation to oversee and manage animal research. Within the institution, the IACUC is primarily charged with this duty, although the ICM husbandry and veterinary personnel have daily oversight of the care of the animal population and animal health.

B. Concerns Involving the Care and Use of Animals

Any person, including any University employee, student, volunteer or member of the general public, may report concerns regarding animal care and use. Concerns may be reported anonymously. Concerns may be submitted to ICM personnel, IACUC members or IACUC staff members in person, via phone or email, or via the IACUC hotline at (718) 601-9104. When reporting a concern, give the date, time, building and room number, individuals involved and description of the incident or condition. The hotline is checked by the IACUC every business day. In emergencies, concerned individuals may call an ICM veterinarian at (917) 232-5319.

The IACUC is required by federal law to review and if warranted, investigate all concerns and if requested, will keep a caller’s identity confidential. Submitted concerns are forwarded to the IACUC Chair, the Attending Veterinarian and the IACUC Executive Director. The IACUC Chair appoints an investigative group to conduct an investigation, which reports the results to the IACUC for review and appropriate action. The IACUC is kept apprised of the status of the investigation until its completion.

The IACUC Chair will forward any recommendations to the appropriate authority (i.e., the ICM Director, a Department Chair, the PI, etc.). The Chair of the IACUC or the IACUC Executive Director will also respond to the individual reporting the concern, if the report is not anonymous. If the matter cannot be resolved through the auspices of the IACUC and the relevant authority, the matter will be referred to the IO and the Vice President for Research Operations and Policy.

C. IACUC

1. Not for Cause Inspections

The IACUC compliance staff performs routine unannounced visits to all laboratories, satellite facilities and ICM procedure rooms in order to assess whether procedures are being conducted in compliance with the approved protocol and all regulations and procedures. If they are not, the IACUC will work with the laboratory staff to inform them of proper procedures and, if required, will provide training or instructions on how to access appropriate training.
2. For Cause Inspections

If the IACUC learns of the possibility that an activity under a Protocol is not being conducted in accordance with the applicable provisions of the Assurance, the PHS Policy, the Guide or, for USDA Animals, the AWA Regulations, it will promptly undertake an investigation into the relevant facts and circumstances. The results of the investigation are discussed at a convened meeting of a quorum of the full Committee. Following the discussion, the IACUC votes to determine what, if any, action, including suspension, is appropriate. Suspension of a previously approved activity requires the affirmative vote of a majority of the quorum present.

Notification of a suspension is sent by the IACUC to the PI and any other party whom the IACUC has determined is responsible, with copies to the EVPR and the Vice President for Research Operations and Policy. The EVPR, in consultation with the IACUC, the Vice President for Research Operations and Policy, the Director of the ICM, the Chair of the IACUC and the IACUC Executive Director, will review the reasons for the suspension, take appropriate corrective actions and, if applicable, report such action to OLAW and/or USDA.

3. Semiannual Reviews

Programmatic Review

Columbia’s Assurance provides that the IACUC must review the Program semiannually during a convened meeting of a quorum of the IACUC, using the PHS Policy, the Guide and, for USDA Animals, the AWA Regulations, as the basis for evaluations. The review is based on information gathered from its inspections (which occur anytime during the six-month period), review of any outside agency inspection reports, review of IACUC membership and activities and discussions with the Director of the ICM and other ICM veterinarians concerning the Program and review of any animal welfare/compliance investigations and any departures from the Guide.

Programmatic review includes, but is not limited to, the following:

- Monitoring the care and use of animals (IACUC functions, record keeping and reporting)
- Veterinary care
- Training of animal care staff and research scientists
- Maintenance of the physical plant
- Occupational health and safety
- Policies for experiments using hazardous agents
- Policies concerning physical restraint and multiple major survival surgical procedures

Facilities Review

The IACUC inspects all animal facilities (including satellite facilities, surgical sites and any other location where animals are brought to, held or housed) at least semiannually, using the
Guide and, for USDA Animals, the AWA Regulations, as the basis for evaluation. If any recommendations are made with respect to any facility managed by the ICM, written correspondence stating these recommendations is sent to the Director and the applicable Associate Director of the ICM and the Facilities Operations Manager requesting a response by a given date. If no response is forthcoming or if an acceptable resolution of a problem cannot be reached, the IACUC refers the matter to the IO with the IACUC’s recommendation for remedying the problem. For all animal study areas other than the ICM facilities, notice of any deficiencies is sent to the PI and the PI is asked to respond by a certain date with a plan and a schedule for remedying all deficiencies. If no response is forthcoming or if the deficiencies are not remedied, the IACUC may refuse to allow the area to continue to be used as an animal study area.

**Semiannual Report**

The IACUC prepares a report of each of its semiannual evaluations resulting from the Program review and inspections described in this Section. Each report describes the nature and extent of Columbia’s adherence to the Guide, the PHS Policy and, for USDA Animals, the AWA Regulations, and any departures from the Guide, the PHS Policy or the AWA Regulations, stating the reasons therefor. The report distinguishes significant deficiencies, if any, from minor deficiencies, and contains a reasonable and specific plan and schedule for correcting such deficiencies. The report is signed by a majority of the IACUC members and includes any minority views. Each report is submitted to IO and the Vice President for Research Operations and Policy.

**4. Adverse Events**

Adverse Events involving USDA Animals are required to be reported to the IACUC via the IACUC Adverse Event Report that can be found in Rascal under “Adverse Events”. An “Adverse Event” is defined as an incident that:

- Threatens the life of an animal, even if it does not result in death;
- Results in the premature or untimely death of an animal; or
- Requires an animal to be euthanized before the intended endpoint of the study.

The Adverse Event Report is completed following the PI’s consultation with a veterinarian. After the Report is received by the IACUC, the Adverse Event is put on the agenda for presentation at the next IACUC monthly meeting.

If a death of a non-USDA Animal occurs in other than normal circumstances relating to animal care procedures, the ICM staff member who discovers the problem must submit an Animal Care Incident Report to the ICM veterinary staff. The Report is then sent to the IACUC for its review. In addition, the investigator must describe the death in a Protocol Modification Data Sheet or a Protocol Continuation Data Sheet.
D. ICM

ICM personnel are available to facilitate research that has been approved by the IACUC and is conducted in accordance with the approved protocol. They can provide guidance in the most humane methods of research and the best research models. They can also provide training on or assistance with the technical aspects of in vivo research. However, the ICM veterinarians are officers of the University and some are members of the IACUC and by virtue of these positions, they must report to the appropriate office Protocol violations or activities that place personnel, animals or the University at risk.
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**GLOSSARY OF ACRONYMS AND ABBREVIATIONS**

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<tr>
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<th>Description</th>
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<tr>
<td>AAALAC</td>
<td>AAALAC International</td>
</tr>
<tr>
<td>APHIS</td>
<td>Animal and Plant Inspection Service, USDA</td>
</tr>
<tr>
<td>AV</td>
<td>Attending Veterinarian</td>
</tr>
<tr>
<td>AWA</td>
<td>Animal Welfare Act</td>
</tr>
<tr>
<td>CUIMC</td>
<td>Columbia University Irving Medical Center</td>
</tr>
<tr>
<td>EH&amp;S</td>
<td>Environmental Health and Safety</td>
</tr>
<tr>
<td>EVPR</td>
<td>Executive Vice President for Research</td>
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<tr>
<td>HHS</td>
<td>Department of Health and Human Services</td>
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<tr>
<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
</tr>
<tr>
<td>IBC</td>
<td>Institutional Biosafety Committee</td>
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<tr>
<td>ICM</td>
<td>Institute of Comparative Medicine</td>
</tr>
<tr>
<td>IO</td>
<td>Institutional Official</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>NYS DOH</td>
<td>New York State Department of Health</td>
</tr>
<tr>
<td>OHP</td>
<td>Occupational Health Program</td>
</tr>
<tr>
<td>OLAW</td>
<td>Office of Laboratory Welfare, NIH</td>
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<tr>
<td>PHS</td>
<td>Public Health Service, HHS</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>SHS</td>
<td>Student Health Services</td>
</tr>
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<td>USDA</td>
<td>U.S. Department of Agriculture</td>
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<tr>
<td>VP&amp;S</td>
<td>Vagelos College of Physicians and Surgeons</td>
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<td>WHS</td>
<td>Workforce Health and Safety (CUIMC)</td>
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Columbia University
Institute of Comparative Medicine
Mouse Wet Lab Class Checklist

Participant Name _____________________   PI ____________________   UNI__________

Ø  **Restraint** (Following demo):
   - Whole body – one handed, two handed methods
   - Tail – base only

Ø  **Anesthesia** (Isoflurane machine discussion):
   - How to use the portable unit
   - Demo: Chamber induction 4%
   - Demo: Maintenance by nosecone at 1-2%

Ø  **Anesthesia** (Cocktail mixture at 0.1mL per 10g body weight or as needed):
   - 1.0 mL ketamine (100mg/mL)
   - 0.4 mL xylazine (20mg/mL)
   - 0.1 mL acepromazine (10mg/mL)
   - 8.5 mL normal saline (0.9%)
   - IP injection
   - Eye protection (apply sterile ophthalmic ointment) & Prevention of hypothermia
   - Monitoring: Toe pinch, respiratory rate, mm color every 10 minutes
   - Local Anesthetics: EMLA cream, lidocaine, bupivicaine
   - Survival Procedures: Redose ketamine only at 30% original dose IP

Ø  **Laboratory Techniques:**
   - Methods for animal identification: Ear notching
     - Permanent marker, ear tag, tattoo, microchip
   - Determining mouse gender
   - Survival Blood Collection Techniques:
     - Submandibular
     - IV – tail prick
     - Hemostasis methods (direct pressure, Kwik stop)
   - Other Injection routes:
     - SC
     - ID (shave and alcohol prep of site)
     - IV (Tail vein)
   - Oral Gavage
   - Cardiac Blood Collection (terminal only)
   - Euthanasia
     - CO2 chamber (3-5 minutes for adults, until respiratory arrest)
     - Secondary Methods: Cervical dislocation & Thoracotomy
   - Perfusion technique

Instructor’s Name _______________________________

Participant’s Signature (Completion) _____________________________   Date ________________
Columbia University  
Institute of Comparative Medicine  
Rat Wet Lab Class Checklist

Participant Name _____________________   PI ____________________      UNI_____________

- **Restraint** (Following demo) DONE
  - Whole body – one handed, two handed methods
  - Tail – base only

- **Anesthesia** (Isoflurane machine discussion): DONE
  - How to use the portable unit
  - Demo: Chamber induction 4%
  - Demo: Maintenance by nosecone at 1-2%

- **Anesthesia**: Ketamine (70-95 mg/kg) + Xylazine (5 mg/kg)
  - IP injection
  - Eye protection (apply sterile ophthalmic ointment) & Prevention of hypothermia
  - Monitoring: Toe pinch, respiratory rate, mm color every 10 minutes
  - Local Anesthetics: EMLA cream, lidocaine, bupivicaine
  - Survival Procedures: Redose **ketamine only** at 30% original dose IP

- **Laboratory Techniques**: DONE
  - Methods for animal identification: Ear notching
    - As demonstrated: Permanent marker, ear tag, tattoo, microchip
  - Determining rat gender
  - Survival Blood Collection Techniques:
    - Saphenous vein
    - Tail prick
    - Hemostasis methods (direct pressure, Kwik Stop)
  - Other Injection routes:
    - SC
    - ID (shave and alcohol prep of site)
    - IV (Tail vein)
  - Oral Gavage
  - Cardiac Blood Collection (terminal only)
  - Euthanasia
    - CO2 chamber (3-5 minutes for adults, until respiratory arrest)
    - Secondary Methods: Thoracotomy

Instructor’s Name _______________________________

Participant’s Signature (Completion) _____________________________   Date ________________

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*Updated October 2019*
## ANIMAL RESEARCH PROGRAM WORKER GRID

### REQUIREMENTS FOR RESEARCH, KM, and IACUC STAFF

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<tr>
<th>Surveillance Procedure</th>
<th>*1 Medical History (baseline + annual)</th>
<th>Physical Examination (baseline)</th>
<th>TB Screening (baseline, Quantiferon or 2 step PPD + annual)</th>
<th>Measles Immunity (baseline)</th>
<th>*2 Rabies Vaccination (baseline + biannually)</th>
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<th>*6 Bloodborne Surveillance (baseline)</th>
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<td>Cats</td>
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<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>A.I.</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Cows, Sheep, or Goats</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>A.I.</td>
<td>no</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>Rabbit/ Rodents</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>A.I.</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Pigs</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>A.I.</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Bats</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>A.I.</td>
<td>no</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>Reptiles</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Fish</td>
<td>required</td>
<td>no</td>
<td>offered</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Amphibias</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Birds</td>
<td>required</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Animal blood &amp; body fluids and unfixed tissues</td>
<td>required</td>
<td>A.I.</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>offered</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

### Abbreviation/ Category Number | Meaning
--- | ---
A.I. | As indicated based on assessment or review of medical history, see Standard of Care Protocol for working with Biosafety Level 3 (BSL-3) and BSL-4;
2 | Offer but not required, employee must sign a waiver if vaccination is declined. Not available at CUIMC Student Health
3 | When required by OSHA regulations, as part of a hearing conservation program as determined by ESHC. Not required. Only available through WHEC.
4 | Only required for women of childbearing age and immunosuppressed staff. Toxoplasma Titer (006478; Toxoplasma Gondii Ab, IgG)
5 | Required annually only when working with ruminants or goats, Q Fever Titer (018771; Q Fever Ab, IgG)
6 | Only when working with human/non-human primate blood products, stem cellassociates: Hepatitis B Immunity (006295; HepB Surface Antibody) or Declination, and Hepatitis C Ab (149859; HCV (Hepatitis C virus) Ab)

*KEY*

Updated October 2019

Annex II-B – Baseline and Periodic Occupational Health Program for Research Staff

Page 75
COLUMBIA UNIVERSITY

Occupational Health Program: Medical Questionnaire Form

Columbia University Health History for Students and Personnel with Animal Contact

Check one box: ☐ IOM ☐ Animal Research Program ☐ Baseline ☐ Periodic

Name: ___________________________ UNI: ___________________________
Date of Birth: __/__/_______ Hire Date: ___________________________
Telephone #: ________________________ Campus Mailing Address: ______________________
Department/Section: ___________________________ Female ☐ Male ☐
Supervisor Name: ___________________________ Office Phone: ____________ Fax #: ____________

Prior to beginning laboratory research with any of the vertebrate species listed below, personnel including students are required to have a brief medical history and physical. Please schedule an appointment as follows:
1. Students are to contact Student Health on their respective campuses e.g. at CUIMC contact 212-305-3400, at Morningside contact 212-854-7426, and Barnard College contact 212-854-2091.
2. Personnel (faculty and staff) are to contact their Supervisor to schedule an appointment with Workforce Health & Safety (WH&S).

Upon completion, WH&S or Columbia Health (Student Health) will provide a “clearance” e-mail to labuc@columbia.edu.

Laboratory Animal Use: (Select which statement is applicable to your status)
☐ 1. I will not handle animals but will be working in areas where animals are housed (administrative and facilities personnel please skip page to #2).
☐ 2. I will be working with animals or animal body parts.
☐ 3. I am involved in veterinary care or animal husbandry.
☐ 4. I am working with human specimens (cells, body fluids, etc.) in conjunction with animal studies.

The following does not apply to Administrative or Facilities Personnel

<table>
<thead>
<tr>
<th>Must be completed by Supervisor or Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Species contact within Columbia University/Barnard (Fill-in all that apply):</td>
</tr>
<tr>
<td>☐ Nonhuman primate (Baboon, Monkey, etc.), please specify_________________________</td>
</tr>
<tr>
<td>☐ Calves, Sheep (state female or male), or Goat, please specify____________________</td>
</tr>
<tr>
<td>☐ Rabbits/Rodents (mice, rats, hamster, gerbil, guinea pig), please specify___________</td>
</tr>
<tr>
<td>☐ Animal blood &amp; bodily fluids &amp; unfixed tissues</td>
</tr>
<tr>
<td>☐ Dogs/Ferrets</td>
</tr>
<tr>
<td>☐ Cats</td>
</tr>
<tr>
<td>☐ Pigs</td>
</tr>
<tr>
<td>☐ Bats</td>
</tr>
<tr>
<td>☐ Reptiles</td>
</tr>
<tr>
<td>2. Frequency of animal contact (select which statement is applicable)</td>
</tr>
<tr>
<td>☐ Daily</td>
</tr>
<tr>
<td>3. For use with live animals ONLY, any work with potential exposure to:</td>
</tr>
<tr>
<td>☐ Bloodborne Pathogens in human-derived materials Yes ☐ No ☐ please list:____________</td>
</tr>
<tr>
<td>☐ Infectious Agents where vaccination is available Yes ☐ No ☐ please list:____________</td>
</tr>
<tr>
<td>☐ Biological toxins where vaccination is available Yes ☐ No ☐ please list:____________</td>
</tr>
</tbody>
</table>

* Principal Investigator signature required*  ___________________________ Date ___________________________

* Principal Investigator Print Name required*  ___________________________ Phone number ___________________________

1 of 3  Updated: 06/06/18 Aston

Updated October 2019

Annex II-C – Health History Form for Students and Personnel with Animal Contact

Page 76
Must be completed by personnel including students:

1. Are you taking any prescription medication? ☐ Yes ☐ No
   If yes, please list: ________________________________

2. Are you immunosuppressed or taking any immunosuppressant drugs? ☐ Yes ☐ No
   Have you had a splenectomy? ☐ Yes ☐ No

3. Do you have any allergies to animals, birds, foods, latex/rubber products or chemicals? ☐ Yes ☐ No
   If yes, please explain: ________________________________
   (Employees with suspected work-related allergies will be evaluated and be referred to the appropriate health care provider by WH&S)

4. Do you have asthma? ☐ Yes ☐ No

5. If female, are you pregnant? ☐ Yes ☐ No

6. If you are in contact with sheep:
   Do you have valvular heart disease, congenital heart defects or prosthetic heart valves? ☐ Yes ☐ No

7. Do you have pre-existing hepatitis? ☐ Yes ☐ No

8. Have you ever had arthritis? ☐ Yes ☐ No

9. Have you ever been diagnosed as having a hernia? ☐ Yes ☐ No

10. Have you ever had back trouble or pain that required treatment or loss of time at work? ☐ Yes ☐ No

11. Do you have any current health problems that may interfere with your duties at work? ☐ Yes ☐ No
    If yes, please describe:

12. Do you have contact with animals outside of work (i.e., pets, wild animals, farm animals)? ☐ Yes ☐ No
    If yes, please describe: ________________________________

13. Have you ever contracted an illness or had a serious injury from an animal or in animal-related work? ☐ Yes ☐ No
    If yes, please explain in detail: ________________________________

14. What is the date of your most recent tetanus vaccine (TT, TD, or Tdap) booster? __________

15. Have you completed a rabies vaccination (3 doses) series? ☐ Yes ☐ No
    If YES, when? __________
    Have you ever had a rabies booster? ☐ Yes ☐ No
    If YES, when? __________

16. If you are in contact with nonhuman primates:
    Have you ever had tuberculosis? ☐ Yes ☐ No
    Have you been vaccinated (BCG) for tuberculosis? ☐ Yes ☐ No
    Have you had a positive reaction to a tuberculin test? ☐ Yes ☐ No
    If you have had a positive reaction to a tuberculin skin test:
    Date of Last Chest X-ray: ____________________________
    Dates of treatment for Latent TB: ____________________

17. Please note any other health history you consider significant:
    ________________________________
    ________________________________
    ________________________________

18. Does this study involve travel outside of the United States? ☐ Yes ☐ No
    If YES, contact Student Health for Travel Assessment prior to travel.

19. If working with Infectious and/or Hazardous Agents/Toxins:
    Are you required to use a respirator? ☐ Yes ☐ No
    If YES, a separate medical questionnaire MUST be completed at WH&S or Columbia Health prior to fit testing.
<table>
<thead>
<tr>
<th>FOR STUDENT HEALTH OFFICE USE ONLY</th>
<th>DATE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculin Skin Test Step 1:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Negative □ Positive mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculin Skin Test Step 2:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Negative □ Positive mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Negative □ Positive mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest X-ray result:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR Titer:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR #1 Vaccine:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR #2 Vaccine:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polio Vaccine #1:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polio Vaccine #2:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT/TD/TDAP Vaccine:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Blood borne Pathogen Surveillance:**

- Hep B Surface Ab: _____________________________
- Toxoplasma Ab, IgG (females working with cats only): ________
- HBV Vaccine #1: _____________________________
- Q Fever Ab, IgG: _____________________________
- HBV Vaccine #2: _____________________________
- Waiver: _____________________________
- HBV Vaccine #3: _____________________________
- HCV Ab (Hep C Virus Antibody): _____________________________
- A: _____________________________
- B: _____________________________
- C: _____________________________
- D: _____________________________

Notes: _______________________________________________________________________________________
_______________________________________________________________________________________________
_______________________________________________________________________________________________

* Faculty/Staff/Student Signature _____________________________ Date _____________________________

* Healthcare Provider/Reviewer Name, Title & Signature _____________________________ Date _____________________________

Updated: 06/06/18 Aston
Columbia University Animal Care Protocol Data Sheet

IACUC ONLY

Submission Date:
Approval Date:
Expiration Date:
Principal Investigator Name:
Faculty Title:

SECTION I. GENERAL INFORMATION

Protocol Number:
Protocol Type:
Being Submitted To:
Is this a triennial protocol?
Previous Protocol Number:
Title:
Originating Department:
Species:

SECTION I-3. FUNDING STATUS

Any funding source from outside Columbia must be listed here. Additionally, protocols funded by the investigator's department must be marked as such.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Funding Details</th>
</tr>
</thead>
</table>

SECTION II. PAIN/DISTRESS CATEGORIZATION

II-1. Check only one category representative of the highest pain/distress level to be experienced in the study.

II-2.

(a) If Category D or E is checked, a literature search for alternative procedures to EACH procedure causing more than momentary or slight pain and/or distress is required. Alleviation of pain during surgical procedures by administration of anesthetics and analgesics does not eliminate the need to address alternatives to the
procedure.

(b) Provide a written narrative description of the results of the literature search. If alternative methods are found, describe why they cannot be used.

For each procedure indicate the procedure, date of search, years covered by the search, databases searched, keywords, and the number of results from each keyword combination, e.g. PubMed, Altweb BIOSIS, CARE Toxline, EMBASE, PsyCInfo, SciSearch, ALTRIB, UCDATInfo, Altweb, Web of Science. The date of search should be no more than three months old.

<table>
<thead>
<tr>
<th>Painless/Distressful Procedure</th>
<th>Date of Search</th>
<th>Years Covered by the Search</th>
<th>Database(s) Searched (must search at least two)</th>
<th>Keyword Combinations</th>
<th># Results from 1st database</th>
<th># Results from 2nd database</th>
</tr>
</thead>
</table>

II-3. Written narrative description of search results and why alternatives cannot be employed:

Additional Alternatives information (Optional):

a. Recognized experts in the field were consulted (MUST provide name, background and affiliation).

b. In highly specialized fields of study, conferences, colloquia, subject expert consultants or other sources may provide relevant and up to date information regarding alternatives in lieu of or in addition to a database search. Provide sufficient documentation such as the subject expert’s qualifications and the date and content of the consult, or the name and date of the conference attended and the subject matter reviewed.

c. Other: details

II-4. ICM veterinarian has been consulted in the planning of procedures (mandatory for pain/distress levels D and E)

Date of Veterinary Consultation:
Name of Veterinarian:

SECTION III. PERSONNEL ROLES/RESPONSIBILITIES & EXPERIENCE/QUALIFICATIONS

III-1. Personnel Roles/Responsibilities & Experience/Qualifications: The Principal Investigator (PI) must assure that all individuals working with animals under this protocol, including the PI, will be appropriately trained. Describe the responsibilities, technical knowledge, and experience that qualifies each person to perform the listed responsibilities.

<table>
<thead>
<tr>
<th>UNI</th>
<th>Name</th>
<th>Role</th>
<th>Species Specific Training</th>
<th>Introduction to ICM</th>
<th>O.H.P. Enroll Date</th>
<th>Regulatory Lecture Date</th>
<th>Edit/View</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Principal Investigator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
III.2. Training of all Personnel: It is the responsibility of the PI to assure that all personnel working with animals on this protocol are trained according to Columbia requirements. ([ICM Training Course Offerings & Wetlabs])

Personnel Training Information

| Name: |
| Course # | Date | Course Title |

III.3 Emergency Contacts (list at least two):

| UNI | Name | Email Address | Office Phone | Lab Phone | Cell Phone |

SECTION IV. NON-ICM ANIMAL HOUSING AND PROCEDURE LOCATIONS

IV.1 Columbia Non-ICM Lab Locations
Will any Columbia non-ICM lab locations be used for animal use procedures, including housing?

Identify all Columbia non-ICM lab locations where animal use procedures (including housing) will be conducted. NOTE: All Columbia non-ICM lab locations must be inspected and approved by the IACUC prior to use.

| Purpose | Building | Floor | Room # | Maximum duration of procedure/ stay in the lab/satellite (hours) | Responsible Person |

IV.2. Laboratory (satellite) animal housing: Housing of animals outside of the ICM animal facilities is strongly discouraged. Requests to do so must be based on scientific reasons that the IACUC will evaluate on an individual basis. The IACUC must also inspect the facility prior to review.

Guideline: Satellite Facility Requirement

a. Will USDA regulated species be housed in a location outside the ICM longer than 12 hours?

If Yes, provide a detailed scientific rationale for such housing AND attach a copy of the management plans for the satellite facilities. (Please go to the Attach Documents section on the left menu to attach your document after saving.)

IV.3. Transportation: Will live animals be transported within Columbia but outside of the ICM animal facilities at any time? Transportation methods must conform to ICM Guidelines.
Guideline: Transportation of Rodents
Guideline: Transportation of Large (non-Rodent) Research Animals

If Yes, complete A-D:

A. Container used for transport:

B. Methods used to protect the animals from infectious agents:

C. Methods used to protect the animals from public visibility:

D. Route and elevator(s) to be used:

IV.4. In ICM managed facilities, are there special needs relative to animal care? Special housing may be required for immunocompromised or pathogen-free rodents, animals receiving carcinogens, infectious agents, radioisotopes, or other hazardous substances, and animals of unknown health status. Additionally, investigators may wish to assume responsibility for administration of special food/water, or food and/or water restriction/deprivation.

To notify ICM ahead of time, please submit an ICM Service Request Form using the link provided below.

If Yes, specify type and responsible personnel:

<table>
<thead>
<tr>
<th>Type</th>
<th>Details</th>
<th>Responsible Person</th>
</tr>
</thead>
</table>

Assumption of Responsibility for Rodent Care Services
http://cumc.columbia.edu/icm/forms/service-request

SECTION V. DRUG, REAGENT, COMPOUND ADMINISTRATION

V-1. Will drugs, reagents, fluids, cells or any other materials be administered to animals? DO NOT include anesthetics, analgesics, tranquilizers or paralytics. List those in the appropriate table(s) below.

NOTE: If no dose such as mg/kg can be provided, e.g. topicals or inhalants, list a concentration in the dose column.

If Yes, provide the following information:

<table>
<thead>
<tr>
<th>Drug/Substance/Concentration if applicable</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
<th>Expected side effects/complications? Other Notes</th>
</tr>
</thead>
</table>

V-2. Will survival or non-survival surgery or other procedures that require the animals to be anesthetized be conducted?
NOTE: For each agent, complete the information for only one anesthetic episode, even if multiple episodes are included in the protocol.

Yes

Drug(s) used for restraint, tranquilization, sedation, anesthesia induction and anesthesia maintenance:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

V-3. If survival surgery is proposed, describe pre-emptive/postoperative analgesia:

<table>
<thead>
<tr>
<th>Analgesia agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If pre-emptive or postoperative analgesia will not be used please provide adequate scientific justification.

V-4. Will a paralytic drug be used?

If Yes, scientifically justify and answer V-5 and V-6:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

V-5. Specify the general anesthetic to be used in conjunction with the paralytics:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

V-6. Describe how the absence of pain/adequacy of anesthesia will be assessed while using paralytics:

V-7. Use of Non-Pharmaceutical Grade Agents in Animals:

Guideline: Use of Non-Pharmaceutical Grade Drugs/Chemicals/Compounds in Research Animals

Will non-pharmaceutical grade drugs, chemicals of substances be used in animals?

Pharmaceutical-grade compound definition:
A pharmaceutical-grade compound (PGC) is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopoeia (e.g., the U.S. Pharmacopeia [USP], British Pharmacopoeia [BP], National Formulary [NF], European Pharmacopoeia [EP], Japanese Pharmacopoeia [JP], etc.). These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy. The Food and Drug Administration (FDA) maintains a database listing of FDA approved commercial formulations for both FDA approved human drugs and veterinary drugs.

If Yes, scientifically justify the use of any non-pharmaceutical grade chemicals/substances AND describe their preparation prior to administration to animals.

NOTE: cost savings alone is not an adequate justification and agents used for analgesia, anesthesia or euthanasia, MUST be of human or veterinary pharmaceutical grade, unless strong scientific justification is provided.

V-8. Controlled Drugs: All drugs in this study that are classified by the Drug Enforcement Administration (DEA) as controlled substances must be stored in a DEA-approved double locked cabinet accessible only to authorized persons, in accordance with DEA regulations.

https://research.columbia.edu/system/files/EHS/Policies/ControlledSubstances.pdf

Are controlled substances being used in this protocol?

If yes, Will anybody other than ICM be administering controlled substances?

SECTION VI. OBJECTIVES AND RATIONALE

VI-1. Research Objectives:

a. Provide a brief (500 words or less), concise summary of the overall objectives of the protocol in lay language. Avoid the use of abbreviations, acronyms and scientific terms. Do NOT cut and paste from a research grant:

b. In 500 words or less, explain the relevance this work will have to human or animal health, the advancement of knowledge and/or the good of society.

c. Please provide a progress report:

VI-2. Rationale for vertebrate animal use:

Why is it necessary to use vertebrate animals in this project rather than alternatives such as use of invertebrates, cell culture or computer simulation?

VI-3. Species justification:

Why was this species chosen for your research? Describe the characteristics of the selected species that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, data from previous studies, or unique anatomic or physiologic features. Cost cannot be used as justification for species selection.
VI-4. Justification of Animal Numbers:

Provide a justification for the number of animals proposed for use in experimental manipulation, for use in breeding (or bred then not needed), and for use in training of personnel. Whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g. provision of power analysis).

NOTE: It is not acceptable to justify the number of animals for one year, and then multiply that number by 3 to arrive at the total number of animals for three years.

Please be thorough in responding to this question. Stating that "the number of animals was selected to achieve statistical significance" is an inappropriate and unacceptable response as references to undocumented "standards" or "requirements". The smallest number of animals required by the study must be used.

Please list the grand total numbers below:

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grand total (three years) of animal numbers for experimental</td>
</tr>
<tr>
<td>Estimated grand total (three years) of number of animals used</td>
</tr>
<tr>
<td>Grand total (three years) of animal numbers for training</td>
</tr>
<tr>
<td>purposes of personnel</td>
</tr>
</tbody>
</table>

SECTION VII: DESCRIPTION OF ANIMAL USE

VII-1. Narrative: Provide a clear and concise sequential written narrative (may attach flow chart) detailing the experimental course each animal will follow from its entry into the study to euthanasia or the end of the study. Note that the IACUC prefers that the word "euthanize" be used in lieu of the word "sacrifice". All groups and all procedures should be included and the chronology of the complete experimental design made clear. Do not include descriptions of in-vitro activities after animal euthanasia. Do not include details of surgical procedures, food or fluid control/restriction, physical restraint, blood collection or tumor monitoring. They should be described in appropriate subsequent sections and need not be repeated here.

VII-2. Are these animals genetically manipulated?

If Yes, describe any anticipated consequences to the animal as a result of genetic manipulation and special care or monitoring that the animals may require:


Is there any scientific justification for excluding the animals in the study from the institution's canine exercise program?

If Yes, provide justification:

VII-4. Enrichment Program: Environmental enrichment produces an environment in which complex stimuli are provided to alleviate the occurrence of abnormal behaviors. Examples include: perches, swings, mirrors, varied food, toys, nesting materials, human interaction, social interaction among members of the same species, or other objects that increase opportunities for expression of species-typical posture and activities and enhance animal well-being. All animals housed in the ICIC central facilities are participants in the established enrichment program.

Is there any scientific justification for excluding the animals in the study from the institution's environmental enrichment program?

If Yes, provide justification:
VII-5. Nutrition: What will animals be fed?
Other: e.g., specially prepared diets, such as semi-synthetics, control diets, vitamin deficient or vitamin excessive diets. Specify the type of diet, provide information on any special handling requirements, and provide manufacturer name.

VII-6. Will access to food be controlled/restricted? (Does not apply to pre-anesthetic fasting)
*Guideline: Regulating Animal Food and Fluid Administration*

If Yes, provide a scientific justification for controlled food access.

a. Describe the procedures for controlled food access and state how long the controlled access will last:

b. Describe how and when you will monitor body weight (NOTE: animals must be weighed at least weekly):

c. Describe other methods for assuring animal well being:

VII-7. Will water be controlled/restricted?
*Guideline: Regulating Animal Food and Fluid Administration*

If Yes, provide a scientific justification for controlled water access:

a. Describe the procedure for controlled water access:

b. Describe how and when you will monitor hydration status:

c. Describe how and when you will monitor body weight (NOTE: animals must be weighted at least weekly):

d. How long will water be withheld?

e. Describe other methods for assuring animal well being:

VII-8. Will restraint be used? NOTE: DO NOT include brief restraint such as for blood collection and injections.
*Guideline for Prolonged Physical Restraint*

If Yes, indicate the type of restraint device and the maximum time each animal would be restrained (e.g. 2 hours per session), and how often the animal will be restrained (e.g. one session every other day for three weeks study duration). The period of restraint should be the minimum required to accomplish the research objectives. Provide justification for the use of restraint:

a. Describe how the animals will be trained/acclimated to the restraint:
b. How often will animals be observed during restraint?

c. Describe the plan if animals fail to adapt to the restraint:

d. What alternatives to the restraint were considered?

VII-9. Will animals be singly housed at any time during the study?

If Yes, please provide scientific justification and state how long the animals will be kept singly housed:

VII-10. Blood Collection. Will blood be collected ante-mortem from animals?

ICM Guideline for Rodent Blood Collection

If Yes, provide the following information:

a. Total blood draw volume per animal:

b. Amount drawn per bleed:

c. Interval between bleeds:

d. Method of collection:

e. Site:

f. Will fluid be administered to compensate for volume loss and if so, describe?

g. If animals are catheterized, describe:

VII-11. Inoculation of Biological Materials: Will the animals be inoculated with biological materials?

Cell Line Testing/Biological Materials for Pathogens

If Yes, which of the following biological materials will be inoculated?

- Tumors
- Cell lines
- Hydridomas
- Embryonic stem cells
- Blood or serum
- Monoclonal or polyclonal antibodies
- Nonpharmaceutical Grade Peptides
- Other, specify.
Describe the selected biological materials:

What are the side effects and treatment of the biological materials selected?

What is the host species origin of these biological materials?
- Mouse
- Rat
- Hamster
- Rabbit
- Human
- Other, specify:

All agents that are infectious to other animals in the colony must be listed in this section
Agent:

Natural host(s):

List any species the agent has the potential to infect including people:

To prevent the possible spread of pathogens into our rodent colonies, all cells, plasma, tissues of animal or human origin and passed through a rodent, and that are to be injected or inoculated into any rodent must be tested for possible rodent pathogens. Test results must be submitted to the Attending Veterinarian or his/her designee for review and approval.

Has the material been tested and if not, will it be?

What procedure (e.g. PCR) was done to evaluate this material for possible rodent pathogens?

VII-12. Tumors: Will experimental animals have tumors induced by the injection of tumor cells or treatment with carcinogens, or are they expected to develop tumors due to genetic manipulations? 
Guideline for Humane Endpoints for Tumor Growth in Rodents

If Yes, answer:

a. At what age or time after treatment will tumors be likely to develop?

b. Describe the target organs or locations where tumors may develop, including potential metastases:

c. Describe how the animals will be monitored for health overall and for tumor progression, including both externally visible and/or internal tumors.
   Please consider using the rat or mouse pre-JACUC approved body condition scoring system.
   Pick "Standard Procedure Descriptions" from the upper left hand menu.

d. Will animals be euthanized and tumors harvested as soon as they are detected?
If No, describe when tumors will be harvested after detection and explain why this endpoint was chosen.

e. If detectable tumors become large in diameter (exceeding 10% total body weight or 2 cm in diameter), interfere with postural adjustments, or if they become necrotic or ulcerated, will animals be euthanized?

If No, explain and justify:

VII-13. Will photography, videography, or similar types of techniques be used to obtain images of animals?

If yes, describe the techniques to be used and state when during the experiments the techniques will be used:

By clicking this box, the principal investigator on this protocol assures that the University “Policies and Procedures for Photography, Videography, and Media Relations involving Animal-Based Research at Columbia University” (link below) will be followed.

If no, provide an explanation:

Policies and Procedures for Photography, Videography, and Media Relations involving Animal-Based Research at Columbia University

VIII. SURGERY

VIII-1. Does the protocol involve any surgeries?

Non-survival Surgery

VIII-2. The type of surgical manipulations is:

Non-survival Surgery

Reference: Surgery Guidelines

VIII-3. Provide a detailed description of the survival or non-survival surgical procedure.

VIII-5. Surgical records must be kept for all species. Records must be complete. It is assumed by both an outside inspector and the IACUC that any activity NOT recorded has NOT been performed. Records must be easily accessible to the IACUC on request. Where will the surgical records be maintained?

VIII-6. Pre-Operative Procedures. Will animals be fasted prior to surgery?

If Yes, for how long?
VIII-7: Which of the following will be performed?

- Clip fur or hair (mandatory for survival and non-survival surgery)
- Remove feathers (mandatory for survival and non-survival surgery)
- Place IV catheter (describe):
- Apply lubricant ointment to eyes
- Scrub site

Name the disinfectant or combination of disinfectants that will be used to prepare the skin for aseptic surgery:

If 'other' please specify:

VIII-8: Expected duration of anesthesia (choose one):

VIII-10: Intra-Operative Monitoring: During the surgical procedure, what method(s) will be employed for monitoring anesthetic depth? Vital signs and anesthesiology monitoring parameters must be recorded every 5-15 minutes. (Check all that apply)

- Respiratory rate + effort
- Palpebral touch (blink reflex)
- Heart rate (ECG)
- Blood pressure
- Toe pinch (withdrawal reflex)
- EEG
- Body temperature
- Pulse oximeter

If 'other' please specify:

Survival Surgery

VIII-2: The type of surgical manipulations is:

Survival Surgery

Reference: Surgery Guidelines

VIII-3: Provide a detailed description of the survival or non-survival surgical procedure.

a. Fully describe pre-emptive and post-operative administration of analgesics for each surgery described. Assure administration aligns with drug section, V-3.

VIII-4: Will there be multiple survival surgeries performed on any animal on this protocol or on any other protocols that animals used under this protocol may be transferred to? (Required if "Survival Surgery" checked in VIII-2 above.)

a. If Yes, provide scientific justification and list the other protocol numbers.
b. If multiple survival surgical procedures are performed on an animal either on this protocol or on any other protocols that animals used under this protocol may be transferred to, describe the sequence and timing AND describe what the maximum number of surgeries of what types any one animal may undergo.

VIII-5: Surgical records must be kept for all species. Records must be complete. It is assumed by both an outside inspector and the IACUC that any activity NOT recorded has NOT been performed. Records must be easily accessible to the IACUC on request. Where will the surgical records be maintained?

VIII-6: Pre-Operative Procedures: Will animals be fasted prior to surgery?

If Yes, for how long?

VIII-7: Which of the following will be performed?

- Clip fur or hair (mandatory for survival and non-survival surgery)
- Remove feathers (mandatory for survival and non-survival surgery)
- Place IV catheter (describe):

  - Apply lubricant ointment to eyes
  - Scrub site

  - Name the disinfectant or combination of disinfectants that will be used to prepare the skin for aseptic surgery:

    If ‘other’ please specify:

VIII-8: Survival surgery on all species must be performed aseptically. What method(s) will be used to sterilize surgical instruments or implanted materials prior to surgery AND between animals if applicable? (Required if “Survival Surgery” checked in VIII-2 above.)

VIII-9: Expected duration of anesthesia (choose one):

VIII-10: Intra-Operative Monitoring: During the surgical procedure, what method(s) will be employed for monitoring anesthetic depth? Vital signs and anesthesia monitoring parameters must be recorded every 5-15 minutes. (Check all that apply)

  - Respiratory rate + effort
  - Palpebral touch (blink reflex)
  - Heart rate (EKG)
  - Blood pressure
  - Toe pinch (withdrawal reflex)
  - EEG
  - Body temperature
  - Pulse oximeter

  If ‘other’ please specify:

VIII-11: Post-Surgical Care: (Required if "Survival Surgery" checked in VIII-2 above.)
a. Describe frequency of observation during anesthesia recovery (must be done continuously unless justification is provided):

b. Describe frequency and duration of observation after anesthesia recovery:

c. Describe postoperative care of surgical incision:

VIII-12: For cannulae, implants, venous catheters and other devices, which will extend through the skin for longer than 12 hours, explain what wound management measures will be taken? (Required if “Survival Surgery” checked in VIII-2 above.)

<table>
<thead>
<tr>
<th>IX. EXPERIMENTAL ENDPOINT CRITERIA, FINAL DISPOSITION AND EUTHANASIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>IX-1. Describe the known or expected adverse effects of the planned procedures on the animals, including those related to genetically modified animals. Describe how the animals will be monitored with regard to known or expected adverse effects.</td>
</tr>
<tr>
<td>IX-2. Describe the final disposition of the animals</td>
</tr>
<tr>
<td>A. Transfer to another approved protocol</td>
</tr>
<tr>
<td>B. Euthanasia</td>
</tr>
<tr>
<td>C. Re-use (explain):</td>
</tr>
<tr>
<td>D. Other (explain):</td>
</tr>
<tr>
<td>IX-3. At what study time point will animals be euthanized?</td>
</tr>
<tr>
<td>Reference: Guidelines for Endpoints in Animal Study Proposals</td>
</tr>
<tr>
<td>IX-4. What clinical signs will be used as criteria for early euthanasia? Early euthanasia implies euthanasia prior to the established experimental endpoint of the study.</td>
</tr>
<tr>
<td>IX-5. Indicate the approved method of euthanasia to be used on these animals as listed in the most recent “Report of the AVMA Panel on Euthanasia.” AVMA Guidelines for the Euthanasia Guidelines for Inhalant and Chemical Methods of Euthanasia Guidelines for Physical Methods of Euthanasia</td>
</tr>
<tr>
<td>Note: If the method cited is not listed as an approved method you must provide the scientific justification for the method including references. Cervical dislocation or decapitation is not to be employed unless justified by scientific necessity. For cervical dislocation, a high degree of technical proficiency must be demonstrated prior to use of the technique. In lieu of demonstrated technical competency, animals must be anesthetized first. For decapitation, equipment must be serviced regularly, blades must be sharp and personnel properly trained.</td>
</tr>
<tr>
<td>Methods of euthanasia:</td>
</tr>
<tr>
<td>Anesthesia</td>
</tr>
<tr>
<td>Carbon Dioxide (CO2) inhalation with secondary method</td>
</tr>
<tr>
<td>Cervical dislocation</td>
</tr>
<tr>
<td>Cervical dislocation with anesthesia</td>
</tr>
</tbody>
</table>

AC-XXXX1234 (Y1 M00)
Decapitation
Decapitation with anesthesia
Euthanex chamber
Euthasol 100 mg/kg
Pithing under anesthesia

IX.S. How will death be ensured after euthanasia (Not Applicable if initial method was decapitation/cervical dislocation)?

NA
Cessation of respiration and heart beat
Decapitation/cervical dislocation
Exsanguination
Bilateral thoracotomy
Other:

X. Hazardous Materials

<table>
<thead>
<tr>
<th>Appendix Type</th>
<th>Appendix Number</th>
<th>Status</th>
</tr>
</thead>
</table>

Will animals be exposed to hazardous agents or radiation?

If Yes, describe and list:

Attached Appendices

Attachments

XI. INVESTIGATOR'S ASSURANCE STATEMENT

By submitting this protocol for consideration I assure the following:

- I am aware of, understand, and will follow the ILAR Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act (AWA) Regulations administered by the United States Department of Agriculture.
- I understand that these regulations and guidelines are applicable to all biomedical research projects using animals that are funded through and administered by Columbia University.
- As required by the Animal Welfare Act Regulations, I hereby assure the IACUC that this experiment does not unnecessarily duplicate previous experiments.
- Furthermore, I will obtain the approval of the IACUC for any significant changes in the experiment before they are implemented.
- I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false statements or departures from the approved procedures may subject me to administrative penalties that include suspension of my animal-based research (AWA 9CFR, ch.1, sect.2.31, par. 8 and FHS policy, document 94-2).
I also certify that the experiments described in this protocol faithfully reflect the work proposed in the sponsored project(s) identified on page one of this application. I have given each person listed in this protocol a copy of the protocol to read. I assure that all personnel listed on this protocol are trained to perform the procedures they are designated for.

**Agreement on electronic submission:**

I understand that this electronic document will be routed to relevant IACUC administrators, safety officers and veterinarians for preliminary screening and then scheduled for review by and distributed to the IACUC. I further understand that once released for approval, the protocol cannot be changed unless a safety officer, veterinarian, or IACUC administrator releases the protocol for further editing by me.

**Principal Investigator Signature**

**Reference:**
- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- Guide for the Care and Use of Laboratory Animals
- Electronic Code of Federal Regulations
Columbia University Animal Care Protocol Data Sheet

IACUC ONLY

Submission Date:
Approval Date:
Expiration Date:
Principal Investigator Name:
Faculty Title:

SECTION I. GENERAL INFORMATION

Protocol Number:
Protocol Type:
Being Submitted To:
Is this a triennial protocol?
Previous Protocol Number:
Title:
Originating Department:
Species:

SECTION I-3. FUNDING STATUS

Any funding source from outside Columbia must be listed here. Additionally, protocols funded by the investigator's department must be marked as such.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Funding Details</th>
</tr>
</thead>
</table>

SECTION II. PAIN/ DISTRESS CATEGORIZATION

II-1. Check only one category representative of the highest pain/distress level to be experienced in the study.
II-2. Check below what alternatives to painful/distressful procedures were considered during the preparation of this protocol/planning of this work. Please choose at least two alternatives.

Note that the term "alternatives" means consideration of the "3Rs" - reduction, replacement, and refinement.

Note that non-animal alternatives should be addressed in the response to question VI-2.

Use of less invasive procedures
Modifications of procedures/husbandry to enhance animal well-being
Maximization of information gained per animal without increasing pain/distress
Reduction of animal numbers to a minimum
Use of an invertebrate species

Provide a narrative (10 sentences or less) regarding the alternatives above that were considered.

Note that non-animal alternatives should be addressed in the response to question VI-2.

II-3. ICM veterinarian has been consulted in the planning of procedures (mandatory for pain/distress levels D and E)

Date of Veterinary Consultation:
Name of Veterinarian:

SECTION III. PERSONNEL ROLES/RESPONSIBILITIES & EXPERIENCE/QUALIFICATIONS

III-1. Personnel Roles/Responsibilities & Experience/Qualifications: The Principal Investigator (PI) must assure that all individuals working with animals under this protocol, including the PI, will be appropriately trained. Describe the responsibilities, technical knowledge, and experience that qualifies each person to perform the listed responsibilities.

<table>
<thead>
<tr>
<th>UNI</th>
<th>Name</th>
<th>Role</th>
<th>Species Specific Training</th>
<th>Introduction to ICM</th>
<th>O.H.P. Enroll Date</th>
<th>Regulatory Lecture Date</th>
<th>Edit/View</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Principal Investigator</td>
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</table>

Describe animal related experience and responsibilities (procedures to be performed by this person)

III-2. Training of all Personnel: It is the responsibility of the PI to assure that all personnel working with animals on this protocol are trained according to Columbia requirements. [ICM Training Course Offerings & Wetlabs]

Personnel Training Information

Name:

<table>
<thead>
<tr>
<th>Course #</th>
<th>Date</th>
<th>Course Title</th>
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III-3 Emergency Contacts (list at least two):

<table>
<thead>
<tr>
<th>UNI</th>
<th>Name</th>
<th>Email Address</th>
<th>Office Phone</th>
<th>Lab Phone</th>
<th>Cell Phone</th>
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AC-XXXX:1234 (Y1 M00)
SECTION IV. NON-ICM ANIMAL HOUSING AND PROCEDURE LOCATIONS

IV-1 Columbia Non-ICM Lab Locations
Will any Columbia non-ICM lab locations be used for animal use procedures, including housing?

Identify all Columbia non-ICM lab locations where animal use procedures (including housing) will be conducted. NOTE: All Columbia non-ICM lab locations must be inspected and approved by the IACUC prior to use.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Building</th>
<th>Floor</th>
<th>Room #</th>
<th>Maximum duration of procedure/stay in the lab/satellite (hours)</th>
<th>Responsible Person</th>
</tr>
</thead>
</table>

IV-2. Laboratory (satellite) animal housing: Housing of animals outside of the ICM animal facilities is strongly discouraged. Requests to do so must be based on scientific reasons that the IACUC will evaluate on an individual basis. The IACUC must also inspect the facility prior to review.

**Guideline: Satellite Facility Requirement**

a. Will non-USDA regulated species be housed in a location outside the ICM longer than 24 hours.

If Yes, provide a detailed scientific rationale for such housing AND attach a copy of the management plans for the satellite facilities. (Please go to the Attach Documents section on the left menu to attach your document after saving.)

IV-3. Transportation: Will live animals be transported within Columbia but outside of the ICM animal facilities at any time? Transportation methods must conform to ICM Guidelines.

**Guideline: Transportation of Rodents**

**Guideline: Transportation of Large (non-Rodent) Research Animals**

If Yes, complete A-D:

A. Container used for transport:

B. Methods used to protect the animals from infectious agents:

C. Methods used to protect the animals from public visibility:

D. Route and elevator(s) to be used:
IV.4. In ICM managed facilities, are there special needs relative to animal care? Special housing may be required for immunocompromised or pathogen-free rodents, animals receiving carcinogens, infectious agents, radioisotopes, or other hazardous substances, and animals of unknown health status. Additionally, investigators may wish to assume responsibility for administration of special food/water, or food and/or water restriction/deprivation.

To notify ICM ahead of time, please submit an ICM Service Request Form using the link provided below.

If Yes, specify type and responsible personnel:

<table>
<thead>
<tr>
<th>Type</th>
<th>Details</th>
<th>Responsible Person</th>
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<tbody>
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</table>

Assumption of Responsibility for Rodent Care Services
http://cumc.columbia.edu/nom/services/service-request

SECTION V. DRUG, REAGENT, COMPOUND ADMINISTRATION

V.1. Will drugs, reagents, fluids, cells or any other materials be administered to animals? DO NOT include anesthetics, analgesics, tranquilizers or paralysis. List those in the appropriate table(s) below.

NOTE: If no dose such as mg/kg can be provided, e.g. topicals or inhalants, list a concentration in the dose column.

If Yes, provide the following information:

<table>
<thead>
<tr>
<th>Drug/Substance/Concentration if applicable</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
<th>Expected side effects/complications? Other Notes</th>
</tr>
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</table>

V.2. Will survival or non-survival surgery or other procedures that require the animals to be anesthetized be conducted?

NOTE: For each agent, complete the information for only one anesthetic episode, even if multiple episodes are included in the protocol.

Drug(s) used for restraint, tranquilization, sedation, anesthesia induction and anesthesia maintenance:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
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</table>

V.3. If survival surgery is proposed, describe pre-emptive/postoperative analgesia:

<table>
<thead>
<tr>
<th>Analgesia agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Maximum Volume per Administration (ml)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
If pre-emptive or postoperative analgesia will not be used please provide adequate scientific justification:

V-4. Will a paralytic drug be used?

If Yes, scientifically justify and answer V-5 and V-6:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
</table>

V-5. Specify the general anesthetic to be used in conjunction with the paralytic(s):

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose (e.g., mg/kg)</th>
<th>Route of administration (e.g., IM, IV)</th>
<th>Number of Doses to be Administered</th>
<th>Time between doses (e.g., minutes, hours)</th>
</tr>
</thead>
</table>

V-6. Describe how the absence of pain/adequacy of anesthesia will be assessed while using paralytics:

V-7. Use of Non-Pharmaceutical Grade Agents in Animals:

Guideline: Use of Non-Pharmaceutical Grade Drugs/Chemicals/Compounds in Research Animals

Will non-pharmaceutical grade drugs, chemicals of substances be used in animals?

Pharmaceutical-grade compound definition:

A pharmaceutical-grade compound (PGC) is defined as any active or inactive drug, biological or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopoeia (e.g., the U.S. Pharmacopeia (USP), British Pharmacopoeia (BP), National Formulary (NF), European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), etc.). These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy. 2 The Food and Drug Administration (FDA) maintains a database listing of FDA approved commercial formulations for both FDA approved human drugs and veterinary drugs.

If Yes, scientifically justify the use of any non-pharmaceutical grade chemicals/substances AND describe their preparation prior to administration to animals.

NOTE: cost savings alone is not an adequate justification and agents used for analgesia, anesthesia or euthanasia, MUST be of human or veterinary pharmaceutical grade, unless strong scientific justification is provided.

V-8. Controlled Drugs: All drugs in this study that are classified by the Drug Enforcement Administration (DEA) as controlled substances must be stored in a DEA-approved double locked cabinet accessible only to authorized personnel, in accordance with DEA regulations.

https://research.columbia.edu/system/files/EHS/Policies/ControlledSubstances.pdf

Are controlled substances being used in this protocol?
If yes, Will anybody other than ICM be administering controlled substances?

SECTION VI. OBJECTIVES AND RATIONALE

VI-1. Research Objectives:

a. Provide a brief (500 words or less), concise summary of the overall objectives of the protocol in lay language. Avoid the use of abbreviations, acronyms and scientific terms. Do NOT cut and paste from a research grant:

b. In 500 words or less, explain the relevance this work will have to human or animal health, the advancement of knowledge and/or the good of society:

c. Please provide a progress report:

VI-2. Rationale for vertebrate animal use:

Why is it necessary to use vertebrate animals in this project rather than alternatives such as use of invertebrates, cell culture or computer simulation?

VI-3. Species justification:

Why was this species chosen for your research? Describe the characteristics of the selected species that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, data from previous studies, or unique anatomic or physiologic features. Cost cannot be used as justification for species selection.

VI-4. Justification of Animal Numbers:

Provide a justification for the number of animals proposed for use in experimental manipulation, for use in breeding (or bred then not needed), and for use in training of personnel. Whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g. provision of power analysis). NOTE: It is not acceptable to justify the number of animals for one year, and then multiply that number by 3 to arrive at the total number of animals for three years.

Please be thorough in responding to this question. Stating that "the number of animals was selected to achieve statistical significance", is an inappropriate and unacceptable response as are references to undocumented "standards" or "requirements". The smallest number of animals required by the study must be used.

Please list the grand total numbers below:

- Grand total (three years) of animal numbers for experimental purposes:
- Estimated grand total (three years) of number of animals used for breeding or bred then not needed:
- Grand total (three years) of animal numbers for training purposes of personnel:

SECTION VII: DESCRIPTION OF ANIMAL USE
VII-1. Narrative: Provide a clear and concise sequential written narrative (may attach flow chart) detailing the experimental course each animal will follow from its entry into the study to euthanasia or the end of the study. Note that the IACUC prefers that the word “euthanize” be used in lieu of the word “sacrifice.” All groups and all procedures should be included and the chronology of the complete experimental design made clear. Do not include descriptions of in-vitro activities after animal euthanasia. Do not include details of surgical procedures, food or fluid control/restriction, physical restraint, blood collection or tumor monitoring. They should be described in appropriate subsequent sections and need not be repeated here.

VII-2. Are these animals genetically manipulated?

If Yes, describe any anticipated consequences to the animal as a result of genetic manipulation and special care or monitoring that the animals may require.

VII-4. Enrichment Program: Environmental enrichment produces an environment in which complex stimuli are provided to alleviate the occurrence of abnormal behaviors. Examples include: perches, swings, mirrors, varied food, toys, nesting materials, human interaction, social interaction among members of the same species, or other objects that increase opportunities for expression of species typical posture and activities and enhance animal well-being. All animals housed in the ICM central facilities are participants in the established enrichment program.

Is there any scientific justification for excluding the animals in the study from the institution’s environmental enrichment program?

If Yes, provide justification:

VII-5. Nutrition: What will animals be fed?

Other; e.g., specially prepared diets, such as semi-synthetics, control diets, vitamin deficient or vitamin excessive diets. Specify the type of diet, provide information on any special handling requirements, and provide manufacturer name.

VII-6. Will access to food be controlled/restricted? (Does not apply to pre-anesthetic fasting)

Guideline: Regulating Animal Food and Fluid Administration

If Yes, provide a scientific justification for controlled food access.

a. Describe the procedures for controlled food access and state how long the controlled access will last:

b. Describe how and when you will monitor body weight (NOTE: animals must be weighed at least weekly):

c. Describe other methods for assuring animal well being:

VII-7. Will water be controlled/restricted?

Guideline: Regulating Animal Food and Fluid Administration

If Yes, provide a scientific justification for controlled water access:

a. Describe the procedure for controlled water access:
b. Describe how and when you will monitor hydration status:

c. Describe how and when you will monitor body weight (NOTE: animals must be weighted at least weekly):

d. How long will water be withheld?

e. Describe other methods for assuring animal well being:

VII-8. Will restraint be used? NOTE: DO NOT include brief restraint such as for blood collection and injections.

_Guideline for Prolonged Physical Restraint_

If Yes, indicate the type of restraint device and the maximum time each animal would be restrained (e.g. 2 hours per session), and how often the animal will be restrained (e.g. one session every other day for three weeks study duration). The period of restraint should be the minimum required to accomplish the research objectives. Provide justification for the use of restraint:

a. Describe how the animals will be trained/acclimated to the restraint:

b. How often will animals be observed during restraint?

c. Describe the plan if animals fail to adapt to the restraint:

d. What alternatives to the restraint were considered?

VII-9. Will animals be singly housed at any time during the study?

If Yes, please provide scientific justification and state how long the animals will be kept singly housed:

VII-10. Blood Collection: Will blood be collected ante-mortem from animals?

_ICM Guideline for Rodent Blood Collection_

If Yes, provide the following information:

a. Total blood draw volume per animal:

b. Amount drawn per bleed:

c. Interval between bleeds:

d. Method of collection:
e. Bite:

f. Will fluid be administered to compensate for volume loss and if so, describe?

g. If animals are catheterized, describe:

VII-11. Inoculation of Biological Materials: Will the animals be inoculated with biological materials?

*Cell Line Testing/Biological Materials for Pathogens*

If Yes, which of the following biological materials will be inoculated?

- Tumors
- Cell lines
- Hyridomas
- Embryonic stem cells
- Blood or serum
- Monoclonal or polyclonal antibodies
- Nonpharmaceutical Grade Peptides
- Other, specify:

Describe the selected biological materials:

What are the side effects and treatment of the biological materials selected?

What is the host species origin of these biological materials?

- Mouse
- Rat
- Hamster
- Rabbit
- Human
- Other, specify:

All agents that are infectious to other animals in the colony must be listed in this section.

Agent:

Natural host(s):

List any species the agent has the potential to infect including people:

To prevent the possible spread of pathogens into our rodent colonies, all cells, plasma, tissues of animal or human origin and passed through a rodent, and that are to be injected or inoculated into any rodent must be tested for possible rodent pathogens. Test results must be submitted to the Attending Veterinarian or his/her designee for review and approval.

Has the material been tested and if not, will it be?
What procedure (e.g. PCR) was done to evaluate this material for possible rodent pathogens?

VII-12. Tumors: Will experimental animals have tumors induced by the injection of tumor cells or treatment with carcinogens, or are they expected to develop tumors due to genetic manipulations?  

Guideline for Humane Endpoints for Tumor Growth in Rodents

If Yes, answer:

a. At what age or time after treatment will tumors be likely to develop?

b. Describe the target organs or locations where tumors may develop, including potential metastases:

c. Describe how the animals will be monitored for health overall and for tumor progression, including both externally visible and/or internal tumors. Please consider using the rat or mouse pre-JACUC approved body condition scoring system. Pick "Standard Procedure Descriptions" from the upper left hand menu.

d. Will animals be euthanized and tumors harvested as soon as they are detected?

If No, describe when tumors will be harvested after detection and explain why this endpoint was chosen.

e. If detectable tumors become large in diameter (exceeding 10% total body weight or 2 cm in diameter), interfere with postural adjustments, or if they become necrotic or ulcerated, will animals be euthanized?

If No, explain and justify:

VII-13. Will photography, videography, or similar types of techniques be used to obtain images of animals?

If yes, describe the techniques to be used and state when during the experiments the techniques will be used:

By clicking this box, the principal investigator on this protocol assures that the University “Policies and Procedures for Photography, Videography, and Media Relations Involving Animal-Based Research at Columbia University” (link below) will be followed.

If no, provide an explanation:

Policies and Procedures for Photography, Videography, and Media Relations Involving Animal-Based Research at Columbia University

VIII. SURGERY
VIII-1. Does the protocol involve any surgeries?

Non-survival Surgery

VIII-2. The type of surgical manipulations is:
Non-survival Surgery

Reference: Surgery Guidelines

VIII-3. Provide a detailed description of the survival or non-survival surgical procedure.

VIII-5. Surgical records must be kept for all species. Records must be complete. It is assumed by both an outside inspector and the IACUC that any activity NOT recorded has NOT been performed. Records must be easily accessible to the IACUC on request. Where will the surgical records be maintained?

VIII-6. Pre-Operative Procedures: Will animals be fasted prior to surgery?

If Yes, for how long?

VIII-7. Which of the following will be performed?

- Clip fur or hair (mandatory for survival and non-survival surgery)
- Remove feathers (mandatory for survival and non-survival surgery)
- Place IV catheter (describe):
- Apply lubricant ointment to eyes
- Scrub site
- Name the disinfectant or combination of disinfectants that will be used to prepare the skin for aseptic surgery:

If 'other' please specify:

VIII-8. Expected duration of anesthesia (choose one):

VIII-10. Intra-Operative Monitoring: During the surgical procedure, what method(s) will be employed for monitoring anesthetic depth? Vital signs and anesthesia monitoring parameters must be recorded every 5-15 minutes. (Check all that apply)

- Respiratory rate + effort
- Palpebral touch (blink reflex)
- Heart rate (ECG)
- Blood pressure
- Toe pinch (withdrawal reflex)
- EEG
- Body temperature
Pulse oximeter
If 'other' please specify:

**Survival Surgery**

**VIII-2: The type of surgical manipulations is:**

Survival Surgery

*Reference: Surgery Guidelines*

**VIII-3: Provide a detailed description of the survival or non-survival surgical procedure.**

a. Fully describe pre-emptive and post-operative administration of analgesics for each surgery described. Assure administration aligns with drug section, V-3.

**VIII-4: Will there be multiple survival surgeries performed on any animal on this protocol or on any other protocols that animals used under this protocol may be transferred to? (Required if "Survival Surgery" checked in VIII-2 above.)**

a. If Yes, provide scientific justification and list the other protocol numbers.

b. If multiple survival surgical procedures are performed on an animal either on this protocol or on any other protocols that animals used under this protocol may be transferred to, describe the sequence and timing AND describe what the maximum number of surgeries of what types any one animal may undergo.

**VIII-5: Surgical records must be kept for all species. Records must be complete. It is assumed by both an outside inspector and the IACUC that any activity NOT recorded has NOT been performed. Records must be easily accessible to the IACUC on request. Where will the surgical records be maintained?**

**VIII-6: Pre-Operative Procedures: Will animals be fasted prior to surgery?**

If Yes, for how long?

**VIII-7: Which of the following will be performed?**

- Clip fur or hair (mandatory for survival and non-survival surgery)
- Remove feathers (mandatory for survival and non-survival surgery)
- Place IV catheter (describe):

Apply lubricant ointment to eyes
Scrub site

Name the disinfectant or combination of disinfectants that will be used to prepare the skin for aseptic surgery:

If 'other' please specify:
VIII-8: Survival surgery on all species must be performed aseptically. What method(s) will be used to sterilize surgical instruments or implanted materials prior to surgery AND between animals if applicable? (Required if "Survival Surgery" checked in VIII-2 above.)

VIII-9: Expected duration of anesthesia (choose one):

VIII-10: Intra-Operative Monitoring: During the surgical procedure, what method(s) will be employed for monitoring anesthetic depth? Vital signs and anesthesia monitoring parameters must be recorded every 5-15 minutes. (Check all that apply)
- Respiratory rate + effort
- Palpebral touch (blink reflex)
- Heart rate (ECG)
- Blood pressure
- Toe pinch (withdrawal reflex)
- EEG
- Body temperature
- Pulse oximeter
- If ‘other’ please specify:

VIII-11: Post-Surgical Care: (Required if "Survival Surgery" checked in VIII-2 above.)

a. Describe frequency of observation during anesthesia recovery (must be done continuously unless justification is provided):

b. Describe frequency and duration of observation after anesthesia recovery:

c. Describe postoperative care of surgical incision:

VIII-12: For cannulae, implants, venous catheters and other devices, which will extend through the skin for longer than 12 hours, explain what wound management measures will be taken? (Required if "Survival Surgery" checked in VIII-2 above.)

IX. EXPERIMENTAL ENDPOINT CRITERIA, FINAL DISPOSITION AND EUTHANASIA

IX-1. Describe the known or expected adverse effects of the planned procedures on the animals, including those related to genetically modified animals. Describe how the animals will be monitored with regard to known or expected adverse effects.

IX-2. Describe the final disposition of the animals

A. Transfer to another approved protocol

B. Euthanasia

C. Re-use (explain):

D. Other (explain):

X-3. At what study time point will animals be euthanized?
Reference: Guidelines for Endpoints in Animal Study Proposals

IX-4. What clinical signs will be used as criteria for early euthanasia? Early euthanasia implies euthanasia prior to the established experimental endpoint of the study.

IX-5. Indicate the approved method of euthanasia to be used on these animals as listed in the most recent "Report of the AVMA Panel on Euthanasia." 
AVMA Guidelines for the Euthanasia
Guidelines for Inhalant and Chemical Methods of Euthanasia
Guidelines for Physical Methods of Euthanasia

Note: If the method cited is not listed as an approved method you must provide the scientific justification for the method including references. Cervical dislocation or decapitation is not to be employed unless justified by scientific necessity. For cervical dislocation, a high degree of technical proficiency must be demonstrated prior to use of the technique. In lieu of demonstrated technical competency, animals must be anesthetized first. For decapitation, equipment must be serviced regularly, blades must be sharp and personnel properly trained.

Methods of euthanasia:
- Anesthesia
- Carbon Dioxide (CO2) inhalation with secondary method
- Cervical dislocation
- Cervical dislocation with anesthesia
- Decapitation
- Decapitation with anesthesia
- Euthanex chamber
- Euthasol 100 mg/kg
- Pithing under anesthesia

IX-6. How will death be ensured after euthanasia (Not Applicable if initial method was decapitation/cervical dislocation)?
- NA
- Cessation of respiration and heart beat
- Decapitation/cervical dislocation
- Exsanguination
- Bilateral thoracotomy
- Other:

X. Hazardous Materials

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<th>Appendix Type</th>
<th>Appendix Number</th>
<th>Status</th>
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</thead>
</table>

Will animals be exposed to hazardous agents or radiation?

If Yes, describe and list:

Attached Appendices

AC-XXXX1234 (Y1 M00)
XI. INVESTIGATOR’S ASSURANCE STATEMENT

By submitting this protocol for consideration I assure the following:

- I am aware of, understand, and will follow the ILAR Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act (AWA) Regulations administered by the United States Department of Agriculture.
- I understand that these regulations and guidelines are applicable to all biomedical research projects using animals that are funded through and administered by Columbia University.
- As required by the Animal Welfare Act Regulations, I hereby assure the IACUC that this experiment does not unnecessarily duplicate previous experiments.
- Furthermore, I will obtain the approval of the IACUC for any significant changes in the experiment before they are implemented.
- I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false statements or departures from the approved procedures may subject me to administrative penalties that include suspension of my animal-based research (AWA 9CFR, ch. 1, sect2.31, par. 8 and PHS policy, document 64-2).
- I also certify that the experiments described in this protocol faithfully reflect the work proposed in the sponsored project(s) identified on page one of this application. I have given each person listed in this protocol a copy of the protocol to read. I assure that all personnel listed on this protocol are trained to perform the procedures they are designated for.

Agreement on electronic submission:

I understand that the electronic document will be routed to relevant IACUC administrators, safety officers and veterinarians for preliminary screening and then scheduled for review by and distributed to the IACUC. I further understand that once released for approval, the protocol cannot be changed unless a safety officer, veterinarian, or IACUC administrator releases the protocol for further editing by me.

Principal Investigator Signature

Reference:
- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- Guide for the Care and Use of Laboratory Animals
- Electronic Code of Federal Regulations
Columbia University Animal Care Protocol Modification Data Sheet

**IACUC ONLY**

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<tr>
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<tr>
<td>Principal Investigator Name:</td>
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<tr>
<td>Faculty Title:</td>
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**SECTION I. GENERAL INFORMATION**

- Protocol Number:
- Protocol Type:
- Being Submitted To:
- Title:
- Originating Department:
- Species:

**Modification Information**

a. Briefly describe modifications to be made AND incorporate the changes. Once you click on the SAVE button at the bottom of the page, you will be able to incorporate the changes into the appropriate section of the protocol form.

If you plan on making major modifications to the protocol (see: Animal Research Handbook, page 30), where the pain level is D or E, the protocol must be sent to the ICM for a veterinary consultation.

Please use this link to do so: https://research.columbia.edu/icm-forms once you have completed your protocol.

If additional potentially painful/distressful procedures are proposed, please update Section II (Pain/Distress Categorization) of this form.

b. Report any mortality and/or complications that occurred during the conduct of the study.
Describe any expected and/or unexpected adverse events that have occurred.
Columbia University Animal Care Protocol Continuation Data Sheet

SECTION I. GENERAL INFORMATION

Protocol Number:
Protocol Type:
Being Submitted To:
Title:
Originating Department:
Species:

Continuation Information

a. Provide a progress report on how the specific aims of the protocol are being met.

b. Briefly describe modifications to be made AND incorporate the changes. Once you click on the SAVE button at the bottom of the page, you will be able to incorporate the changes into the appropriate section of the protocol form.

If you plan on making major modifications to the protocol (see Animal Research Handbook, page 30), where the pain level is D or E, the protocol must be sent to the ICM for a veterinary consultation.

Please use this link to do so: https://research.columbia.edu/ism-forms once you have completed your protocol.

If additional potentially painful/distressful procedures are proposed, please update Section II (Pain/Distress Categorization) of this form.

c. Report any mortality and/or complications that occurred during the conduct of the study. Describe any expected and/or unexpected adverse events that have occurred.

d. What was the total animal usage to date, not including animals used for breeding or bred then not needed?

e. What was the total animal usage to date for animals used for breeding or bred then not needed?
f. Please provide the number of animals transferred from other Columbia protocols and/or imported from other institutions.
How To Access the Animal Facility

**Workforce Health & Safety**

- **Obtain Health Clearance**
  - Students: MS – Columbia Student Health Services
  - CUMC – CUMC Student Health Services
  - Barnard – Barnard Health

**Students**

- Bring the protocol approval email to Joanne McCormick in BB1810.
  - For JLG
    - Access is requested by ICM following barrier training

**Access to ICRC**

If trying to gain access to the ICRC, meet with the building supervisor Mrs. Veronica Ifill to obtain a personal access code.

**Access to JLG**

If access to eye scanners at JLG is required, please email zicm@columbia.edu

**Attend the Laboratory Animal Regulatory Lecture given by the IACUC**

- Complete the “Introduction to the Institute of Comparative Medicine” (course # TC0900) via RASCAL’s training center
- Complete the species-specific training via RASCAL’s training center
- Pass the quiz

**Sign up for the hands-on facility or barrier training via ICM’s website**

*NOTE to all Mouse users:
Please bring the barrier completion certificate to the hands-on barrier training!

**Complete Hands-on Mouse or Rat Wetlab Register via ICM’s website**

- https://research.columbia.edu/content/icm-barrier

**Mouse & Rat Users**

**Mouse Users**

- CUMC Barrier Training (Course#TC0550) via RASCAL’s training center
- Pass the Quiz

**All researchers who anesthetize animals**

- Rodent anesthesia and analgesia CBT(Course#TC2750) via RASCAL’s training center
- Pass the Quiz

**Attend Rodent Aseptic Surgery Training**

Register via ICM’s website: https://cumc.co1.qualtrics.com/jfe/form/SV_dmAQN5Gnx9VdweF

NOTE: RASCAL course #TC1550 is a prerequisite for the hands-on training
Institute of Comparative Medicine Medical Waiver Form for
Visitors Exposed to Laboratory Animals or Animal Tissue, and/or who have Access to Areas Where
Animals are Housed or Used

Overview:
Research animal facilities present unique health and safety risks to people. The intent of this document is to make
you aware of these risks and to encourage you to ask questions or seek clarification prior to entering the Columbia
University research animal facilities. The risks of injury and/or exposure have been divided into 4 different risk
groups.

Risk of Injury and/or Exposure:
- **Low Risk:** Amphibians, aquatic, and reptiles
- **Mild Risk:** Rats, mice, rabbits, guinea pigs, hamsters, gerbils, birds, and swine - mild risk of injury, but significant
  potential for allergies.
- **Moderate Risk:** Dogs, sheep, cattle – moderate risk of injury, zoonotic disease potential (Rabies, Q Fever, and
  bacterial, viral, and fungal infections), and significant potential for allergies.
- **Marked Risk:** Non-human primates: marked risk of injury, zoonotic disease (B Virus, Tuberculosis, viral hepatitis,
  infections); must have had a negative TB test within the 6 months of entry into the non-human primate area.

Allergies:
Exposure to mice, rats, guinea pigs and other rodents, and rabbits can lead to allergic symptoms such as runny nose,
redden, watery, or inflamed eyes, dermatitis, or asthma. Persons with pre-existing allergies may be predisposed to
develop allergies to laboratory animals or have more severe reactions. Please consult your physician or a
healthcare professional at Workforce Health and Safety if you are allergic to animals or have asthma.

Caution: *Infectious (e.g. zoonotic) diseases represent a known risk to individuals exposed to laboratory
animals and to those who have access to areas where they are housed or used.*

Note: Women who are pregnant should be aware that infected animals may pose a danger to the fetus. If you are
pregnant, please discuss the potential risks with a healthcare professional at Workforce Health and Safety.

Provisions have been implemented to minimize exposure to allergens and zoonotic diseases and to minimize
injuries. They include both engineering practices and use of personal protective equipment (PPE). Engineering
controls include the use of air filtration and directional airflow. PPE requirements may include donning gowns,
labatory coats, or coveralls, surgical masks, face shields, safety glasses, gloves, shoe covers, and hair bonnets.

Eating, drinking, or the application of cosmetics is also not permitted within the vivarium.

My signature below indicates that I am 18 years of age or older, and I have read and fully understand the risks
posed by entering animal research areas, and/or handling animals or animal tissue. I agree to follow the prescribed
practices when working in the vivarium and understand that failure to comply with the prescribed practices may
lead to removal from the vivarium.

Print Name: ________________________________

Signature: ________________________________ Date: ________________________________

PLEASE RETURN COMPLETED FORM TO: ICM, c/o Ms. Joanne McCormack, BB-1810

*Individuals who are not CUMC employees or students or are listed on an approved CUMC IACUC protocol and will have
temporary contact with animals or animal or human tissue for a period of time not to exceed 7 days. These individuals are
enrolled in a health surveillance program at their own institution. All others must complete a medical history questionnaire and
make an appointment with Workforce Health & Safety.

Revised: March 2016
ICM NEW ARRIVAL CAGE CARD
ICM NON-RFID CAGE CARD

PI: Shoulson, Rhvka
Supplier: Charles River Labs
Batch ID: 00131-00058
Protocol: AAAN2752
Delivery Date: 13-Jul-2015
Responsible: Shoulson, Rhvka

P/N: UR007116-01-MAAN2752-HP2752-A1
Species/Strain: Mouse C57BL6J; female
Criteria: 0-30d of gestation 15-02524, Females, 2-5 wks gestation
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**Passenger Information**

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**ICM RFID Cage Card**

- **Shrinkon, Optima**: AAAN2752
- **Model**: 1128Y
- **Part Number**: AAAA123
- **Lot Number**: BBBB234
- **Expiration Date**: 12/31/2023

**Passenger Information**

- **Name**: John
- **Part Number**: 12345
- **Description**: Cage Card
- **Quantity**: 100
- **Lot Number**: AAAA123
- **Expiration Date**: 12/31/2023

**Passenger Information**

- **Name**: Alice
- **Part Number**: 67890
- **Description**: Cage Card
- **Quantity**: 50
- **Lot Number**: BBBB234
- **Expiration Date**: 06/30/2024
ICM SEPARATED CAGE CARD

INVESTIGATOR: ____________________  PROTOCOL #: ____________________

DATE FLAGGED: ____________________  DATE SEPARATED #: ____________________

ROOM #: ____________________  NUMBER OF CAGES Mode: ____________________

COMMENTS: ____________________
ICM SERVICE REQUISTION CAGE CARD

Front

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- Cage Changing by PI ONLY: Start/End Date /
- Special Diet: Start/End Date /
- Special Water: Start/End Date /
- Food Restriction/Deprivation (please circle) Start/End Date /
- Water Restriction/Deprivation (please circle) Start/End Date /
- Note to ICM: |

(Over)

Back

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Updated November 2020  Annex VII-A – ICM Service Requisition Cage Card  Page 120
ICM SICK ANIMAL CAGE CARD
(VETERINARY TECHNICIAN)

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Accommodation # 26705

Updated November 2020
ICM MORTALITY CAGE CARD

INVESTIGATOR:
DATE FOUND: ROOM:
CAGE ID / RACK:
# OF:
ADULT: WEANLING: PUP:

HOLD #: INITIALS:
ICM POST OPERATIVE CAGE CARD

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<th>Emergency Contact</th>
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<td>Other Medications [drug, dose (mg/kg), route]</td>
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</tbody>
</table>

- ID: L (clean/injured), UDG (read/writeout/discharge), SD
- Dietary: Debrieve, notify ICM II if SD or SD
- Animal Condition: Active, I: Inactive, S: Moribund
- Feeding: 3rd day, notify ICM II if SD
- If an animal differs in recovery from its classmates, please individually document in "Comments".
- Note: Anesthetic drugs given as scheduled in approved protocol. Also include any 'other medications' given. If multiple medications are given, use a number system to indicate which one(s) was given.

Updated November 2020  Annex VII-D – ICM Post Operative Cage Card Page 124
ICM EUTHANASIA CAGE CARD

AUTHORIZED BY
PRINT NAME: ________________________
# Departmental Accident Report Form

for Workers’ Compensation Benefits

## Employee Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Employee ID</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>Home Phone</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City, State, ZIP</td>
<td></td>
</tr>
<tr>
<td>Employment Date</td>
<td></td>
</tr>
<tr>
<td>CU Department</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
</tr>
<tr>
<td>Work Phone</td>
<td></td>
</tr>
<tr>
<td>Act #:</td>
<td></td>
</tr>
<tr>
<td>Wages per week</td>
<td></td>
</tr>
<tr>
<td>Days per week worked</td>
<td></td>
</tr>
<tr>
<td>Regular Days Off</td>
<td></td>
</tr>
</tbody>
</table>

## Accident Information

To be completed by the employee—**all questions required**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of injury/illness</td>
<td></td>
</tr>
<tr>
<td>Time of injury/illness</td>
<td></td>
</tr>
<tr>
<td>Time you started work</td>
<td></td>
</tr>
<tr>
<td>Location (building, room)</td>
<td></td>
</tr>
<tr>
<td>What were you doing when injury/illness occurred?</td>
<td></td>
</tr>
<tr>
<td>How did the injury/illness occur?</td>
<td></td>
</tr>
<tr>
<td>Was the injury caused by a sharp object (needle, scalpel, razor, etc.)? If so, you must specify the device type and brand:</td>
<td></td>
</tr>
<tr>
<td>Describe the object or substance (chemical, blood, etc.) which directly injured you:</td>
<td></td>
</tr>
<tr>
<td>Describe the injury/illness—indicate type of injury, specify left or right, and so on, for example, “upper right leg”:</td>
<td></td>
</tr>
<tr>
<td>To whom did you report the accident?:</td>
<td></td>
</tr>
<tr>
<td>Date Reported</td>
<td></td>
</tr>
<tr>
<td>Time reported</td>
<td></td>
</tr>
<tr>
<td>Witness’s Name</td>
<td></td>
</tr>
<tr>
<td>Witness’s address</td>
<td></td>
</tr>
</tbody>
</table>

## Supervisor’s Statement

To be completed by the supervisor

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was employee paid for the full day?</td>
<td></td>
</tr>
<tr>
<td>Is employee losing time?</td>
<td></td>
</tr>
<tr>
<td>Employee’s first day away from work:</td>
<td></td>
</tr>
<tr>
<td>Has employee returned to work?</td>
<td></td>
</tr>
<tr>
<td>Is employee a union member?</td>
<td></td>
</tr>
<tr>
<td>Expected date of return to work:</td>
<td></td>
</tr>
<tr>
<td>Will the employee be paid for lost time?</td>
<td></td>
</tr>
<tr>
<td>Did the injured employee receive medical attention?</td>
<td></td>
</tr>
<tr>
<td>Name and address of doctor or hospital where first treated:</td>
<td></td>
</tr>
<tr>
<td>Who investigated the accident?:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Title:</td>
<td></td>
</tr>
<tr>
<td>Work Phone:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Supervisor’s discussion with employee on HOW TO PREVENT THIS TYPE OF INJURY/ILLNESS:</td>
<td></td>
</tr>
</tbody>
</table>

## Signatures

I CERTIFY THAT THE ACCIDENT INFORMATION PROVIDED ABOVE IS TRUE.

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMPLOYEE Signature</td>
<td></td>
</tr>
<tr>
<td>Date (mm/dd/yyyy)</td>
<td></td>
</tr>
<tr>
<td>Supervisor’s comments:</td>
<td></td>
</tr>
<tr>
<td>SUPERVISOR Signature:</td>
<td></td>
</tr>
<tr>
<td>Date (mm/dd/yyyy)</td>
<td></td>
</tr>
</tbody>
</table>
COLUMBIA UNIVERSITY ANIMAL HANDLERS ILLNESS/ACCIDENT FORM

Individual will take this form to Health Services at Columbia in John Jay when seeking medical attention for conditions which occur when he/she is on duty related to experimental animals.

TO BE COMPLETED BY PHYSICIAN/NURSE PRACTITIONER/NURSE:

S.S.N.: ____________________________

Individual’s Name: ____________________________ CU UNI Number: ________________

Position/Job Title: ____________________________

Medical Attention is Being Requested For: ____________________________

Is This Illness or Injury Related To Work With Animals? Yes □ No □

If the Above Answered is YES, Give: DATE _____ TIME _____ LOCATION ______

Signed By: ____________________________ Department: ____________________________

Title: ____________________________ Date: ____________________________

Time Left Work: ____________________________

Nature of Illness or Injury: __________________________________________________________

________________________________________________________________________

Does This Illness or Injury Appear to Be Related to This Individual’s Job as an Animal Handler?

________________________________________________________________________

Able To Return to Work Immediately? Yes □ No □

If Yes, Restrictions (If Any): __________________________________________________________

Probable Length of Illness or Injury: ____________________________

________________________________________________________________________

Additional Comments: __________________________________________________________

________________________________________________________________________

All Illnesses or Accidents Related To Work with Animals are Required to be Reported to the Office of Environmental Health and Radiation Safety and the Workers Compensation Board.

Signature: ____________________________ Title: ____________________________

Date: ____________________________ Time Examined: ____________________________

Updated November 2020

Annex VIII-A-2–Animal Handlers Illness/Accident Form (Morningside)
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