



Care and Use of Live Vertebrate Animals in Research and Teaching

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Vertebrate Animals in Research and
Teaching
Responsible Executive: Senior Vice
Provost for Research and Institutional
Official (Ithaca Campus Units)
Responsible Offices: Cornell Center for
Animal Resources and
Education/Institutional Animal Care and
Use Committee/Office of Research
Integrity and Assurance (Ithaca Campus
Units)
Originally Issued: May 8, 2002
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POLICY STATEMENT

Cornell University regards the use of animals in research, teaching, and testing to be an integral component of continued progress in science, education, and agriculture. The university expects all of its animal facilities and programs to maintain the highest standards of animal care and use, and to be operated in accordance with applicable federal, state, and local laws, regulations, policies, and guidelines.

REASON FOR POLICY

The university is committed to the highest ethical standards of animal care and use. This policy outlines the principles that govern the humane conduct of activities involving live vertebrate animals, procedures that ensure compliance with external regulations and the responsible use of Cornell resources, and establishes roles and responsibilities of those individuals who are involved in the care and use of animals in research, testing and teaching.

ENTITIES AFFECTED BY THIS POLICY

- All units of the university. Weill Cornell Medical Center and Graduate School of Medical Sciences will administer this policy under Weill Cornell procedures.

WHO SHOULD READ THIS POLICY

- All faculty, postdoctoral fellows, graduate and undergraduate students, research and teaching personnel, and staff members involved in the care and use of live vertebrate animals.
- Heads of units where live vertebrate animals are housed or used in research, teaching, or testing.
- Institutional Animal Care and Use Committee members

WEB ADDRESS FOR THIS POLICY

- This policy:
- University Policy Office: www.policy.cornell.edu

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

CONTENTS

Policy Statement	1
Reason for Policy	1
Entities Affected by This Policy	1
Who Should Read This Policy	1
Web Address for This Policy	1
Contents	2
Related Resources	3
Contacts	4
Definitions	5
Responsibilities, Ithaca Campus Units	7
Principles	12
Overview	12
Procedures, Ithaca Campus Units	13
Components of Cornell's Animal Care and Use Program	13
Institutional Official (IO)	13
Attending Veterinarian	13
Cornell University Institutional Animal Care and Use Committee (IACUC)	14
Occupational Health and Safety for Animal Users	15
Veterinary Care Program	15
Cornell Animal Facilities	16
Use of Animals in Instruction	20
Submission, Maintenance, Review, and Approval of Proposed Animal Activities	21
Recordkeeping and Reporting	22
Procedure for Reporting Violations of this Policy	23
Appendix A: Lines of Responsibility, Ithaca Campus Units	24
Index	25

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RELATED RESOURCES

University Policies and Documents Applicable to All Units of the University

[University Policy 1.7, Financial Conflicts of Interest in Research](#)

[University Policy 4.6, Standards of Ethical Conduct](#)

University Policies and Documents Applicable to Only Ithaca Campus Units of the University

[Institutional Animal Care and Use Committee \(IACUC\) Policies](#)

[AUHSP Policies and Procedures](#)

External Regulations, Guidance and Documentation

[Animal Care Policy Manual \(USDA, 2016\)](#)

[Animal Welfare Act \(1966\)](#)

[Animal Welfare Act Regulations \(9 CFR, Chapter 1, Subchapter A\) \(2009\)](#)

[AVMA Guidelines for the Euthanasia of Animals: 2013 Edition](#)

[Guide for the Care and Use of Agricultural Animals in Research and Teaching \(2010\)](#)

[Guide for the Care and Use of Laboratory Animals \(National Research Council, 2011\)](#)

[Health Research Extension Act of 1985, Public Law 99-158](#)

[IACUC Guidebook, Second Edition, \(Office of Laboratory Animal Welfare, National Institutes of Health, 2002\)](#)

[New York State Public Health Law \(Article 5, Title 1, Section 504\)](#)

[Occupational Health and Safety in the Care and Use of Research Animals \(NRC, 1997\)](#)

[Public Health Service Policy on Humane Care and Use of Laboratory Animals \(2002\)](#)

[United States Fish and Wildlife Service Permits for Field Studies](#)

[United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training \(2002\)](#)

POLICY 1.4

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Institutional Official (Ithaca
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Responsible Offices : Cornell
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Committee/Office of Research
Integrity and Assurance (Ithaca
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Care and Use of Live Vertebrate Animals in Research and Teaching

CONTACTS

Direct any general questions about this policy to your college or unit's administrative office. If you have questions about specific issues, call the following offices:

Contacts, Ithaca Campus Units

Subject	Contact	Telephone	Email/Web Address
Animal Welfare Assurance	Office of Research Integrity and Assurance	(607) 255-5398 Fax (607) 255-0758	www.oria.cornell.edu
Chemical and Laboratory Safety, Radiation Safety, Biological Safety, Waste Disposal	Environmental Health and Safety	(607) 255-8200	dehs@cornell.edu www.ehs.cornell.edu
Occupational Health and Safety	Occupational Medicine, Gannett Health Services	(607) 255-5155	www.gannett.cornell.edu/services/occupational/
Regulatory Compliance	Office of Research Integrity and Assurance	(607) 255-5398 Fax (607) 255-0758	www.oria.cornell.edu
Regulatory Oversight, Research Protocols, Facilities Inspections, Animal Welfare Concerns, Animal Users Health and Safety Program	Institutional Animal Care and Use Committee	(607) 255-5398	iacuc@cornell.edu www.iacuc.cornell.edu
Veterinary Care, Program Administration	Cornell Center for Animal Resources and Education	(607) 253-4378	care@cornell.edu www.research.cornell.edu/care
Violations of this Policy	Office of Research Integrity and Assurance	(607) 255-5398 Fax (607) 255-0758	iacuc@cornell.edu
	Cornell University Hotline	(866) 293-3077 (toll-free)	hotline.cornell.edu

Contacts Weill Cornell Campus Units

Subject	Contact	Telephone	Email/Web Address
All Questions	Research Animal Protections Program		iacuc@med.cornell.edu

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

DEFINITIONS

These definitions apply to these terms as they are used in this policy.

“Ag Guide”	The Federation of Animal Science Societies’ 2010 <i>Guide for the Care and Use of Agricultural Animals in Research and Teaching</i> (and any subsequent editions).
Animal	Any living, non-human, vertebrate animal (mammal, bird, reptile, amphibian, or fish), unless otherwise specified.
Animal and Plant Health Inspection Service (APHIS)	Part of the U.S. Department of Agriculture responsible for administering the Animal Welfare Act (see definition below). For more information, see www.aphis.usda.gov .
Animal Care (AC)	A program of APHIS.
Animal Facility	A Cornell University owned and operated facility where vertebrate animals are housed or held for a 12-hour period or more.
Animal Users Health and Safety Program (AUHSP)	A Cornell University program that assesses the human-health risks associated with direct and indirect contact with animals used in research and teaching. The objective of the AUHSP is to ensure that health risks for every individual are managed to an acceptable level.
Animal Welfare Act and Regulations (AWAR)	Administered at Cornell by APHIS, a federal law that requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public.
Animal Welfare Assurance (“Assurance”)	A key document in defining the relationship between the institution and the Public Health Service (PHS); signed by the institutional official, the assurance sets forth the responsibilities and procedures of the institution regarding the care and use of animals, and requires the institutional official to file an annual report with the PHS. An “Assurance” can remain in place up to four years and is renewable.
Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)	A private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. For more information, see www.aaalac.org .
Attending Veterinarian (AV)	A veterinarian with training or experience in the care and management of the species attended, and who has direct or delegated authority for activities involving animals at Cornell University.
Center for Animal Resources and Education (CARE)	A service for Cornell’s Ithaca campus units responsible for administering the Animal Care and Use in compliance with state and federal regulations and university policy. For more information, see www.research.cornell.edu/care .
Faculty Member	A member of the university faculty as defined by the <i>Bylaws of Cornell University</i> . For more information, see trustees.cornell.edu .
Institutional Animal Care and Use Committee (IACUC)	A committee at Cornell responsible for overseeing the Animal Care and Use program and monitoring its compliance with applicable federal and state regulations and appropriate guidelines. For more information, see www.iacuc.cornell.edu (Ithaca campus units).
Institutional Official (IO)	The individual at Cornell who is authorized to commit legally on behalf of the university that the requirements of the Animal Welfare Act and

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

DEFINITIONS, CONTINUED

	<i>the Public Health Service Policy on Humane Care and Use of Laboratory Animals</i> are met.
Investigator	The individual who uses, or supervises the use of, live vertebrate animals on a project.
Office of Laboratory Animal Welfare (OLAW)	The division of the NIH responsible for developing, monitoring, and exercising compliance with the <i>PHS Policy</i> (see definition below). For more information, see grants1.nih.gov/grants/olaw/olaw.htm .
Office of Research Integrity and Assurance (ORIA)	The Cornell department responsible for managing, administering, monitoring, and assessing Cornell's research compliance programs for the Ithaca-based campuses
Principal Investigator (PI)	In the context of this policy, the individual with primary responsibility for a project, including designing and implementing research, teaching, or testing activities involving live, vertebrate animals. For more information, see the Principal Investigator Eligibility policy applicable for the Ithaca campus at www.research.cornell.edu/vpr/policies/pi-policy.html .
Protocol	A description of the proposed procedures involving live vertebrate animals. For more information about protocols for the Ithaca-based campuses, see https://www.iacuc.cornell.edu/requirements/about-the-process.htm
Public Health Service (PHS)	A division of the U.S. Department of Health and Human Services that includes the NIH, Food and Drug Administration, and Centers for Disease Control and Prevention, among others. For more information, see http://usphs.gov/aboutus/agencies/hhs.aspx
PHS Policy	The <i>PHS Policy on Humane Care and Use of Laboratory Animals</i> (2002) implements the Health Research Extension Act of 1985. For more information, see grants1.nih.gov/grants/olaw/references/phspol.htm .
"The Guide"	The National Research Council's <i>Guide for the Care and Use of Laboratory Animals</i> .
USDA	United States Department of Agriculture

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RESPONSIBILITIES, ITHACA CAMPUS UNITS

Animal Facility Managers

Apply standards as established by the director of Center for Animal Resources and Education (CARE) and Cornell's accreditation consistently to the operation of the animal facility and to care of the animals.

Ensure that users requesting access to the facility are appropriately trained in the policies and procedures related to the facility.

Ensure that all animal handlers working in the facility have completed and are current with the Animal Users Health and Safety Program requirements before starting work.

Provide information to visitors on potential risks associated with entrance to each animal facility.

Accompany visitors in animal facilities.

Maintain records of and report on a monthly and annual basis to the Institutional Animal Care and Use Committee (IACUC) office the number of animals used on animal protocols; inform principal investigators (PIs) of the status of animals used vs. approved by the IACUC; work with the PIs to ensure that animal numbers are not exceeded.

Center for Animal Resources and Education (CARE) Veterinarians

Maintain a program of adequate veterinary care consisting of monitoring and assessment of animal well-being and effective management of the following:

- Animal procurement and transportation
- Preventive medicine (including quarantine, animal biosecurity, and surveillance)
- Clinical disease, disability, or related health issues, and assessment of animal well-being
- Protocol associated disease, disability, and other sequelae
- Pain and distress
- Euthanasia

Advise on the design and performance of experiments using animals as related to model selection, collection, and analysis of samples and data from animals, and methods and techniques proposed or in use.

Provide guidance and give direction to investigators and all personnel involved in the care and use of animals to ensure appropriate husbandry, handling, medical treatment, immobilization, sedation, analgesia, anesthesia, and euthanasia, provided such intervention is not precluded in an approved IACUC protocol.

Provide guidance and oversight to surgery programs including use of appropriate anesthetics and analgesics, and pre- and post-operative care, involving animals.

Assist in the review of all animal use protocols.

Participate in facility inspections.

Assist in the review of institutional programs involving animals in research, testing, and teaching.

Chair, Institutional Animal Care and Use Committee (IACUC)

Oversee the IACUC's review and approval, modification, or disapproval of animal use protocols, annual review of protocols, and amendments to protocols.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RESPONSIBILITIES, ITHACA CAMPUS UNITS, CONTINUED

Supervise every six months a review of the institution's program for animal care, use, and inspection of all animal facilities.

Prepare and sign off on the semiannual report to the institutional official (IO).

Make recommendations to the IO pertaining to IACUC membership.

Through the IO, submit an annual report to National Institutes of Health (NIH)/Office of Laboratory Animal Welfare (OLAW)/U.S. Department of Agriculture (USDA)/New York State Department of Health.

Investigate and prepare a report to OLAW, submitted through the IO, of all reportable incidents.

Evaluate reports of potential violations to existing animal care and use regulations or this policy, and investigate and report findings to the full membership of the IACUC.

In consultation with the IACUC, review the reasons for any activity that leads to suspension of a protocol, take appropriate corrective action, and report that action to regulatory and accreditation agencies, as needed.

College Dean/Unit Head

Oversee the physical facilities housing its animals in compliance with all federal and state laws.

Work closely with the director of CARE to monitor the operation of the animal facility and care of the animals for consistency with the standards established by the director of CARE and Cornell's accreditation.

Sustain a program of regular maintenance in all animal facilities in accordance with this policy.

Seek the input of the director of CARE during the managers' annual performance review.

Seek input from the director of CARE at the time of the college/department annual budget planning with respect to priorities for ongoing maintenance or capital expenditures for animal facilities.

Confer with Director of CARE to ensure that appropriate animal facilities are available for potential new hires and research or teaching programs, prior to making employment offers.

Provide funds to renovate and/or equip animal facilities as necessary for new hires/programs.

Director of CARE and Attending Veterinarian

Ensure that the university's Animal Care and Use program meets, at a minimum, the standards of care required by the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (2002) ("PHS Policy") and Animal Welfare Act and Regulations (AWAR).

Oversee procedures to assure accommodation of animal housing in currently approved animal facilities unless extenuating circumstances require new housing accommodations. Advise Senior Vice Provost for Research on requests for new housing facilities.

Participate in the planning and design of any construction or renovation involving animal facilities.

Review and approve all final plans for animal housing and procedure spaces.

Participate in the oversight of all renovations to and construction of animal housing and procedure spaces.

Oversee all animal facilities.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RESPONSIBILITIES, ITHACA CAMPUS UNITS, CONTINUED

Keep supervisors and department chairs and/or program directors informed of problems or concerns relating to the management of animal facilities in their respective areas of responsibility.

Participate in selecting and hiring staff for any nonacademic position whose responsibilities will include managing an animal facility.

Serve as an ex-officio voting member of the IACUC.

Responsible for maintaining accreditation for Cornell's animal program through the Association for Assessment and Accreditation of Laboratory Animal Care International.

◆**Note:** The director of CARE is the attending veterinarian and a CARE veterinarian with associated responsibilities as outlined in this policy.

Director, Office of Research Integrity and Assurance (ORIA)

Provide regulatory oversight for ensuring that Cornell's Animal Care and Use program is compliant with applicable regulatory requirements.

Coordinate activities with other compliance committees where they intersect with animal care and use program.

Lead for-cause audits for incidents of alleged noncompliance with this policy and IACUC policies and report outcomes to the IACUC and the IO.

Ensure prompt institutional response to detected problem and necessary and timely reporting to regulatory agencies.

Institutional Animal Care and Use Committee (IACUC)

Review at least once every six months the institution's program for animal care and use, using the AWAR, *The Guide*, and the *Ag Guide* (see Definitions) as a basis for evaluation.

Inspect at least once every six months all of the institution's animal facilities and animal procedure spaces, using the AWAR and *The Guide* as a basis for evaluation. Submit to the IO reports of the above evaluations.

Review and investigate concerns involving the care and use of animals at the university resulting from complaints or from reports of noncompliance received from university personnel and the public.

Make recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training.

For all activities involving the use of animals in research, testing, and teaching, monitor whether scientific merit has been demonstrated in accordance with the requirements of the U.S. government's *Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, Principle II, which states, "Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society."

Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals.

Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Conduct annual reviews of protocols.

Suspend an activity involving animals if it does not comply with the AWAR, *The Guide*, *PHS Policy*, or Cornell University's *Animal Welfare Assurance* ("Assurance") approved by the NIH/OLAW.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RESPONSIBILITIES, ITHACA CAMPUS UNITS, CONTINUED

	<p>Conduct, or establish requirements for conducting, orientation of investigators, students, postdoctoral fellows, technicians, and animal care workers on the principles surrounding the use of animals, and the requirement to use animals in a humane and sensitive manner.</p> <p>Through the IO, report to the Animal and Plant Health Inspection Service (APHIS)/Animal Care (AC) and any federal funding agency in writing within 15 days, whenever the institution fails to adhere to a reasonable plan and schedule for correcting a significant deficiency in the institution's program or facilities.</p> <p>Evaluate findings of investigations of potential violations to existing animal care and use regulations or this policy.</p> <p>Maintain records in accordance with this policy.</p> <p>Approve and promulgate Animal Care and Use Procedures (ACUP) and IACUC policies.</p>
Institutional Animal Care and Use Committee (IACUC) Staff	<p>Provide administrative support for IACUC-related activities to the IACUC and the IO.</p> <p>Communicate IACUC requirements to the PI.</p> <p>Ensure timely and accurate reporting to external regulatory agencies.</p> <p>Serve as information resource for investigators and IACUC members regarding regulatory issues, IACUC requirements, and the status of applications to the IACUC.</p> <p>Coordinate semiannual IACUC facility inspections.</p> <p>Perform other professional duties, including training of new IACUC members, grant proposal reviews, drafting IACUC policies and procedures, and executing the Post Approval Quality Assurance program for protocols involving animal use.</p> <p>Maintain IACUC records in accordance with regulatory requirements.</p>
Institutional Official (IO)	<p>Legally commit on behalf of the university that the university will meet the requirements of the AWAR.</p> <p>Sign Cornell University's <i>Assurance</i> that commits the university to meet the requirements of the <i>PHS Policy</i>.</p> <p>Make recommendations to the president regarding appointment of IACUC members.</p> <p>Ensure that the program goals of quality animal care and use are in alignment with the university's missions.</p> <p>Monitor university compliance with all applicable animal welfare laws, regulations, and policies.</p> <p>Ensure that the number and type of animal facilities are maintained at the minimum necessary to assure animal welfare, provide research support resources necessary to advance research and teaching, allow for support staff efficiencies, minimize costs to researchers and campus, and ensure accreditation.</p> <p>Sign forms, reports, and letters on behalf of the university, and interact with the IACUC in overseeing Cornell's Animal Care and Use program.</p> <p>On receipt of inspection reports, semiannual reports, incident reports, and recommendations from the IACUC, determine, in consultation with the IACUC, whether deficiencies are significant or minor and whether appropriate corrective actions have been identified and implemented.</p>

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

RESPONSIBILITIES, ITHACA CAMPUS UNITS, CONTINUED

	<p>Review and submit animal care and use related registrations, annual reports, and any other required reports to the external regulatory agencies.</p> <p>Consult with the IACUC regarding suspensions and corrective actions; report to regulatory and funding agencies.</p> <p>Monitor whether all personnel involved in animal care, treatment, and use are qualified to perform their duties and that both training and instruction in specific areas are provided.</p> <p>Ensure that the university has an attending veterinarian who provides adequate veterinary care to Cornell's animals.</p>
Investigator (Principal Investigator, Co-Investigator, or Investigator)	<p>Abide by the policies of the IACUC.</p> <p>Submit a request to the IACUC, in the form of a completed eSirius application, for approval of any animal work that is conducted under their supervision. Where appropriate, provide evidence that alternatives to such procedures have been considered, including potential use of non-animal or in vitro systems, refinement of research techniques designed to decrease or eliminate pain and distress, and reduction in the number of animals required to obtain scientifically valid data through better experimental design. Ensure that the information provided in the application is complete, accurate, and in sufficient detail so as to enable the IACUC to make a determination of the humane care and use of the animals. Start animal work only after notice of IACUC approval is received in writing from the IACUC office.</p> <p>Request approval from the IACUC for changes to approved studies through a protocol amendment, and implement those changes only after receipt of written approval from the IACUC.</p> <p>Report annually the status of each protocol and assure that ongoing activities are conducted in accordance with the approved protocol.</p> <p>Resubmit each protocol for de novo IACUC review at least once every three years if animal work is continuing. Ensure that IACUC approval for the renewal is granted before the initial approval has expired, or suspend animal work until approval of the renewal has been obtained in writing by the IACUC.</p> <p>Maintain compliance with the approved protocol in the conduct of the animal work.</p> <p>Follow all applicable facility policies and procedures in the conduct of the animal work in the facilities.</p> <p>Promptly notify the IACUC and CARE of any unexpected results that affect the welfare of the animals under their animal program. Report any unanticipated pain or distress, morbidity, or mortality to the CARE veterinarian and the IACUC.</p> <p>Ensure that all experiments involving live animals are performed under their supervision or that of another qualified scientist as approved by the IACUC. Ensure that personnel involved in animal use in the animal project are approved to do so by the IACUC, and trained in proper procedures in animal handling, administration of anesthetics and analgesics, aseptic technique, post-operative monitoring, and euthanasia.</p> <p>Maintain clinical health and protocol procedural records in accordance with this policy.</p>
Senior Vice Provost for Research	<p>Serve as Institutional Official for Ithaca campus units.</p>

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PRINCIPLES

Overview

Cornell University regards the use of animals in research, teaching, and testing to be an integral component of continued progress in science, education, and agriculture. The use of animals in research, teaching, and testing has been essential for advances in the life sciences, medicine, and agriculture and has resulted in enormous benefits for human and animal health. The university is committed to the highest ethical standards of animal care. Each Cornell investigator or instructor wishing to use animals on or off campus must conduct all animal work in accordance with all laws, regulations, and policies governing the care and use of animals.

◆**Note:** The clinical care of client-owned animals at the Cornell University Hospital for Animals, located on the Ithaca campus, is not covered by this policy.

Animal facilities and programs will be operated in accord with the U.S. Department of Agriculture Animal Welfare Act (1966), Regulation (C.F.R., 2009) and policies, the Health Research Extension Act (1985), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS, 2002), the Guide for the Care and Use of Laboratory Animals (NRC, 2011), the Guide for the Care and Use of Agricultural Animals in Research and Teaching (2010), the New York State Health Law (Article 5, Section 504), and other applicable federal, state, and local laws, regulations, policies, and guidelines.

Cornell University is committed to accreditation of its Animal Care and Use program by the Association for Assessment and Accreditation of Laboratory Animal Care International. A fundamental premise of accreditation is the maintenance of a consistently high standard of care for all animals used in research, teaching, and testing at Cornell.

For Ithaca campus units, the Cornell Center for Animal Resources and Education has authority over all physical facilities holding or housing vertebrate animals, and is expected to work with each college or unit having such facilities to see that the facilities are in compliance with all federal and state laws, and to sustain a program of regular maintenance in all animal facilities in accordance with this policy.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS

Components of Cornell's Animal Care and Use Program

The following segments of this document outline generally the components of Cornell University's Animal Care and Use program, which is designed to comply with federal regulations. For a graphical representation of lines of responsibility, see Appendix A. Additionally, more detailed responsibilities and procedures are contained in the responsibilities section of this policy.

Institutional Official (IO)

The senior vice provost for research serves as the Institutional Official (IO) for Ithaca campus units.. Cornell University's Institutional Animal Care and Use Committee (IACUC) and the Attending Veterinarian report to the IO, who has the administrative and operational authority to commit institutional resources to ensure compliance with the regulations that govern Cornell's Animal Care and Use program (for more detail, see Responsibilities).

Attending Veterinarian

Adequate veterinary medical care is an essential component of the university's animal care and use program, and is required by the *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals* (2002) ("*PHS Policy*") and Animal Welfare Regulations. The university has an attending veterinarian (AV), who must be qualified by virtue of appropriate postgraduate training and/or experience in laboratory animal science and medicine. The AV is a voting member of the IACUC. The AV has the authority to execute the duties inherent in assuring the adequacy of veterinary care and overseeing other aspects of animal care and use. The AV's clinical veterinary care responsibility is delegated to clinical veterinarians and veterinary technologists who are part of the Center for Animal Resources and Education (CARE) veterinary staff. If approved by the AV, the primary clinical care of Cornell-owned animals can be provided by a non-CARE veterinarian/species expert under a current Letter of Agreement (LOA) between the non-CARE veterinarian(s)/species expert(s) and the AV, detailing mechanisms of direct communication and appropriate record keeping. Where there are concerns about animal welfare or imminent danger to animals or human health, if the non-CARE veterinarian is not available, or if agreement cannot be reached, the AV/CARE veterinarian has authority to act to protect the health and well-being of institutional animals and will make the final decision regarding the disposition of the animal (for more detail, see Responsibilities).

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

Cornell University Institutional Animal Care and Use Committee (IACUC)

The IACUC is appointed by the president of the university, upon the recommendation of the senior vice provost for research and that of the dean of the faculty and is qualified through the experience and expertise of its members to oversee the university's animal program, facilities, and procedures in accordance with the applicable regulations (for more detail, see Responsibilities).

Federal regulations require that the membership of the IACUC include, at a minimum, a veterinarian, a scientist experienced in research involving animals, a member whose principal expertise is in a nonscientific field of study, and an individual not affiliated with Cornell.

- Because Cornell is a large institution, membership beyond the minimum required by regulation is drawn from faculty and staff of the colleges and divisions of the university to provide ample representation of investigators, to reflect the diversity of the institution's research portfolio, and to accommodate the workload associated with reviewing a large number of protocols and conducting facility inspections. Ordinarily, the membership of IACUC at Cornell includes at least the following members:
 - One faculty member, College of Agriculture and Life Sciences
 - One faculty member, College of Veterinary Medicine
 - One faculty member, College of Human Ecology
 - One faculty member, College of Arts and Sciences
 - One non-scientist
 - One research or animal care technician, manager or supervisor
 - At least one member not affiliated with the university*
 - The Attending Veterinarian
 - The biosafety officer, Environmental Health and Safety, whose role includes bringing human health and safety issues to the attention of the committee

*The nonaffiliated members represent general community interests in the proper care and use of animals, are not laboratory animal users affiliated with the university, or immediate family members of a person who is affiliated with the university.

Membership terms are for three years (except for the AV and biosafety officer, who are *ex officio* with voting privileges).

Alternates are also appointed as necessary, will attend meetings when a regular member is unable to attend, and will have all rights of the regular member.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

The president appoints the chair from the faculty members who have served at least one year on the IACUC, upon the recommendation of the senior vice provost for research.

Occupational Health and Safety for Animal Users

Cornell University has an Animal Users Health and Safety Program (AUHSP). The objective of the AUHSP is to ensure that health risks for every individual associated with direct and indirect contact with animals used in research, testing and teaching at Cornell are managed to an acceptable level. All individuals involved in the care and use of Cornell animals must complete the AUHSP requirements specific to them as a condition of access to Cornell animals and animal facilities.

Veterinary Care Program

The program of veterinary care consists of assessment of animal well-being and effective management of the following components:

- Animal procurement and transportation: Evaluate potential vendors for the quality of animals they provide and review the health history; ensure that for all types of transportation, animal safety and well-being are maintained, and an appropriate level of biosecurity is provided.
- Preventive medicine: Assess need for, and implement, appropriate quarantine, animal biosecurity, and surveillance to maintain healthy animals and minimize non-protocol sources of variation associated with disease and inapparent infection.
- Clinical disease, disability, or related health issues, and assessment of animal well-being: All animals are observed daily by a person or persons qualified to verify their well-being. Concerns are communicated to the CARE veterinary staff. Appropriate treatment or control measures, including euthanasia if indicated, are instituted following diagnosis of an animal disease or injury, in conjunction with the principal investigator (PI). Disease surveillance including routine monitoring of colony animals for the presence of parasitic, bacterial, and viral agents is performed on a regular schedule depending on species and studies being performed.
- Protocol-associated disease, disability and other sequelae: If possible, the CARE veterinarian will discuss the situation with the PI to determine a course of action consistent with experimental goals. However, where there are concerns about animal welfare or imminent danger to animals or human health, if the PI is not available, or if agreement cannot be reached, the CARE

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

veterinarian has authority to act to protect the health and well-being of institutional animals.

- Surgery, pre- and post-operative care, pain and distress, anesthesia and analgesia, euthanasia: CARE veterinarians have the responsibility and authority to ensure that handling, restraint, anesthesia, analgesia, and euthanasia are administered as required to relieve pain and suffering in research animals, provided that such intervention is not specifically precluded in protocols reviewed and approved by the IACUC. This includes monitoring and providing recommendations concerning preoperative procedures, surgical techniques, the qualifications of personnel to perform surgery, and the provision of postoperative care.

Cornell Animal Facilities

The Provost vests oversight responsibility for the institutional Animal Care and Use program, including the operation of animal facilities, with the senior vice provost for research who serves as Institutional Official (IO), and the director of CARE who reports to the senior vice provost for research/IO or designee.

The senior vice provost for research must approve the use of any Cornell animal facility and must ensure that the number and type of campus animal facilities are maintained at the minimum necessary to assure animal welfare and advance research and teaching while ensuring staff efficiencies, cost minimization, and maintained accreditation.

Animals may be housed in a facility only after the IACUC has inspected and approved it for animal use.

New Animal Facilities

All animals will be housed in existing Ithaca campus unit ("campus") animal facilities or a non-Cornell owned facility if approved by the IACUC. Adding animal facilities to Cornell's already existing centralized program of animal care and use is costly, with significant one-time construction or renovation expenses, new and ongoing operating and maintenance expenses, and often increases in per diems. Proliferation of animal facilities poses risks to providing appropriate animal care, effectively supporting researchers, and maintaining accreditation.

New animal facilities at Ithaca campus units will be considered only if animal welfare impacts and scientifically justified research requirements cannot be addressed through renovation or other means of remediation of current facilities or changes to research protocols.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

Requests to consider new animal facilities must be made by the department head and the college dean to the Senior Vice Provost for Research. The director of CARE will consult with the researcher, department administration, and college to determine the research needs and the options for utilizing current facilities. The director of CARE will advise the senior vice provost for research on the details of the assessment, including cost, staffing, animal welfare, and necessary research infrastructure. The director of CARE will provide cost estimates to the college dean/unit head and department chair. The senior vice provost for research will also consult with the IACUC chair, the researcher, the dean/unit head and department chair, and others as necessary to make a final determination.

The cost of renovation and construction must be covered by the department/college. In cases where the facility will be used primarily by one researcher, department, or college, the maintenance, utilities, staffing and other costs that are not covered by per diems will not be included in campus allocated research costs and instead must be covered by the college and/or department.

No commitments of new animal facilities may be made to potential or current investigators without the approval of the senior vice provost for research and agreement by the college dean/unit head to cover the corresponding financial commitment.

◆ Note: The use of non-human primates in research and other scientific purposes can provide unique and important models for human and animal health. The pursuit of such research also requires sophisticated and costly infrastructure and expertise to assure animal welfare and to protect researchers and animal care staff from zoonotic risks. This infrastructure is not currently in place on the Ithaca campus, therefore, the use of non-human primates for research, teaching, or testing is not allowed on the Ithaca-based campuses. Any potential change in this position will require the engagement of campus leadership, including but not limited to the President, Provost, Senior Vice Provost for Research, and the Directors of CARE and ORIA. Such discussions, which will have to balance the costs against the societal and institutional benefits of the research and also assess the value of alternative use of the requisite university resources in support of other research, will likely be lengthy. o

No action may be taken related to employment or admission offers, proposal submission, or any other planning for use of non-human primates on the Ithaca campus until these deliberations are first requested by interested parties, and then

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

completed with institutional decisions made by the President and Provost regarding any change in this position.

Management and Operation (for more detail, see Responsibilities)

IACUC must review at least once every six months the institution's program for animal care and use, using the Animal Welfare Act Regulations (AWAR), Guide for the Care and Use of Laboratory Animals ("Guide"), and the Guide for the Care and Use of Agricultural Animals in Agriculture and Research ("Ag Guide") as a basis for evaluation. The Guide is used as the primary standard for facilities and program evaluations for research that meets the federal "biomedical" definition. For agricultural animals that are used in biomedical research, the IACUC assesses the user goals, procedures and concern for animal welfare based on the animal use proposed in the protocol, to determine whether a farm or laboratory setting is most appropriate. Thus, regardless of the "biomedical" or "agricultural" nature of the animal work, when the IACUC determines that a farm setting is most appropriate for the conduct of the animal work, the Ag Guide is used as a resource for facilities and program evaluations. The appropriateness of the housing setting is determined and approved by the IACUC as part of the protocol review.

CARE has authority over all Ithaca campus unit physical facilities holding or housing vertebrate animals. CARE is directly responsible for the management and operation of certain of these animal facilities at Cornell, generally those supporting behavioral/biomedical research, while other animal facilities, generally those associated with agricultural research, fall under the day-to-day operation of the colleges. The director of CARE oversees all animal facilities.

For the director of CARE to achieve standards of animal care and use at Cornell that meet the principles of humane care and use of animals and are compliant with federal regulations and the accreditation standards of the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC):

- The director of CARE will keep supervisors and department chairs and/or program directors informed of problems or concerns regarding the management of animal facilities in their respective areas of responsibility. The director of CARE and the colleges will maintain open lines of communication as they partner to facilitate the research, teaching, and production programs of the college and departments.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

- Managers of animal facilities operated by CARE will report to the director of CARE.
- For nonacademic managers of animal facilities not directly managed and operated by CARE:
 - The director of CARE, or a designated representative, will participate in the selection and hiring decision for any nonacademic position whose responsibilities include managing an animal facility.
 - The manager will have a secondary, or indirect, reporting relationship to the director of CARE. The importance and rationale for this indirect reporting relationship will be conveyed to the managers in writing, for instance, a letter of appointment or reappointment, and this reporting relationship will be noted explicitly in the formal university position description for the facility management position.
 - Supervisors of nonacademic managers of animal facilities, not operated by CARE, will seek the input of the director of CARE during the managers' annual performance review.
- Academic staff members who directly supervise an animal facility are expected to work closely with the director of CARE to ensure that the operation of the animal facility and care for the animals is consistent with the standards established by Cornell and through accreditation by AAALAC.

College/departments should confer with CARE at the time of annual budget planning with respect to priorities for ongoing maintenance or capital expenditures for animal facilities.

Planning and Design

All animal housing and procedure spaces must be in full compliance with current regulations and standards, including U.S. Department of Agriculture and AAALAC.

The director of CARE or a designee, must participate in the planning and design of any construction or renovation involving animal facilities. The CARE representative must review and approve all final plans prior to implementation.

Visitation

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

For reasons of health, safety, and security, animal facilities generally are not open to the public. Applications for public tours may be made to CARE, the manager of the facility, and the PI(s), who must all give consent. If a tour is approved, all visitors are subject to the provisions of the AUHSP. Only IACUC approved animals are allowed in Cornell animal facilities.

Use of Animals in Instruction

Vertebrate animals serve as an invaluable aid in instruction. It is recognized, however, that some students have ethical objections to the use of vertebrate animals in this manner. Courses that use vertebrate animals are identified as such in the course descriptions. Students who have concerns about the use of animals in these courses should consult the course instructor for more information about the precise ways in which the animals are used.

Guidelines for Faculty and Students on the Use of Animals in Instruction

For demonstrating certain principles and procedures, the use of animals in teaching is recognized as an invaluable, often essential, pedagogical device.

1. All animal use proposed or planned for classroom instruction must be approved by the Cornell IACUC.
2. For courses in which vertebrate animals are to be used in dissection, surgery, or in other experimental procedures, the course description that appears in the *Courses of Study* catalog should alert students to this fact.
3. A detailed description of the intended use of vertebrate animals should be available to students upon request from the instructor of each course. This intended animal use must be approved by the IACUC in an animal protocol describing such use.
4. Faculty should instruct students in the responsible use of animals.
5. Faculty members are encouraged to explain their reasons and need for using vertebrate animals, and should indicate to students the availability of the procedures described in item eight below.
6. Students are encouraged to discuss their concerns about the instructional use of vertebrate animals with the instructor in the course.
7. When consistent with pedagogical objectives, faculty members are encouraged to consider adopting alternative methods and procedures that do not involve the use of live animals.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

8. When students object on ethical or other valid grounds to participating in an exercise using vertebrate animals, instructors are encouraged to provide alternative means for learning the same material when consistent with pedagogical objectives.
9. A student who is reluctant to voice his or her concerns about animal use in a particular course, or who thinks these concerns have not received proper attention, may seek assistance from the chair of the IACUC at 255-5398, or by e-mail at iacuc@cornell.edu.

Submission, Maintenance, Review, and Approval of Proposed Animal Activities

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use, and must review proposed animal activities to ensure that the criteria for humane care and use of animals established in the *PHS Policy* and Animal Care Regulations are implemented and followed. In its review of these proposals, the IACUC's primary goal is to facilitate compliance with Cornell policies, and applicable laws and regulations consistent with the pursuit of appropriate and productive scientific endeavors. The method and schedule for submission, review, approval, and maintenance of these proposals (including initial use protocols, amendments, three-year renewals and annual reviews) by the Cornell IACUC is outlined in IACUC policies.

The PI must complete and submit a protocol for the use of live vertebrate animals, for research, teaching, or testing. No animal activity can begin until a written notification of approval is issued by the IACUC chair or her/his designee.

PIs submitting protocols for review requiring that animals be subject to more than momentary or slight pain or distress must provide evidence that alternatives to such procedures have been considered, including potential use of non-animal or in vitro systems, refinement of research techniques designed to decrease or eliminate pain and distress, and reduction in the number of animals required to obtain scientifically valid data through better experimental design.

Studies will be approved for a period of 36 months subject to annual reviews, after which time a new and complete protocol for the use of live vertebrate animals must be submitted.

The IACUC conducts an annual review of the protocol. The investigator is required to report annually on the status of the protocol and that ongoing activities are conducted in accordance with the approved protocol.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

No changes to the procedures approved by the IACUC on a protocol can be implemented until an amendment is submitted and reviewed by the IACUC and a written approval for the amendment has been issued. The type of review required for an amendment may vary depending on the nature of the amendment.

The protocol for the use of live vertebrate animals is considered the intellectual property of the PI, available only for confidential use by IACUC members and reviewers. Accordingly, no individual may be given access to the protocol without the explicit permission of the PI.

Recordkeeping and Reporting

Cornell University maintains recordkeeping and reporting requirements related to the animal care and use program in accordance with *PHS Policy*, AWAR, and requirements of AAALAC accreditation.

Records that relate directly to protocols, such as protocol form, IACUC review documentation, amendments, and annual reviews, - must be kept for the duration of the activity and for an additional three years after completion of the activity. Records documenting such activities conform to the recommendations of *The Guide* and with commonly accepted professional standards.

Animal Procedural and Health Records

Records documenting such activities as the provision of adequate veterinary care and occupational safety as it pertains to animal use are expected to conform to the recommendations of *The Guide* and with commonly accepted professional standards. The PI is responsible for keeping the following records:

- Accurate and complete animal identification, health, and procedural records must be maintained for all animals used on a protocol. Records should be readily available to inspectors, veterinary staff, and animal care staff.
- For all species, animal husbandry and health records must be retained until final disposition of the animal (e.g., euthanized, transferred, adopted) unless required otherwise by the IACUC or the AV. In addition, dog and cat records and reports must be maintained for three years after a study is completed. Procedural records should be kept at a minimum of three years, or after the publication of all research manuscripts resulting from that study.

POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

PROCEDURES, ITHACA CAMPUS UNITS, CONTINUED

Procedure for Reporting Violations of this Policy

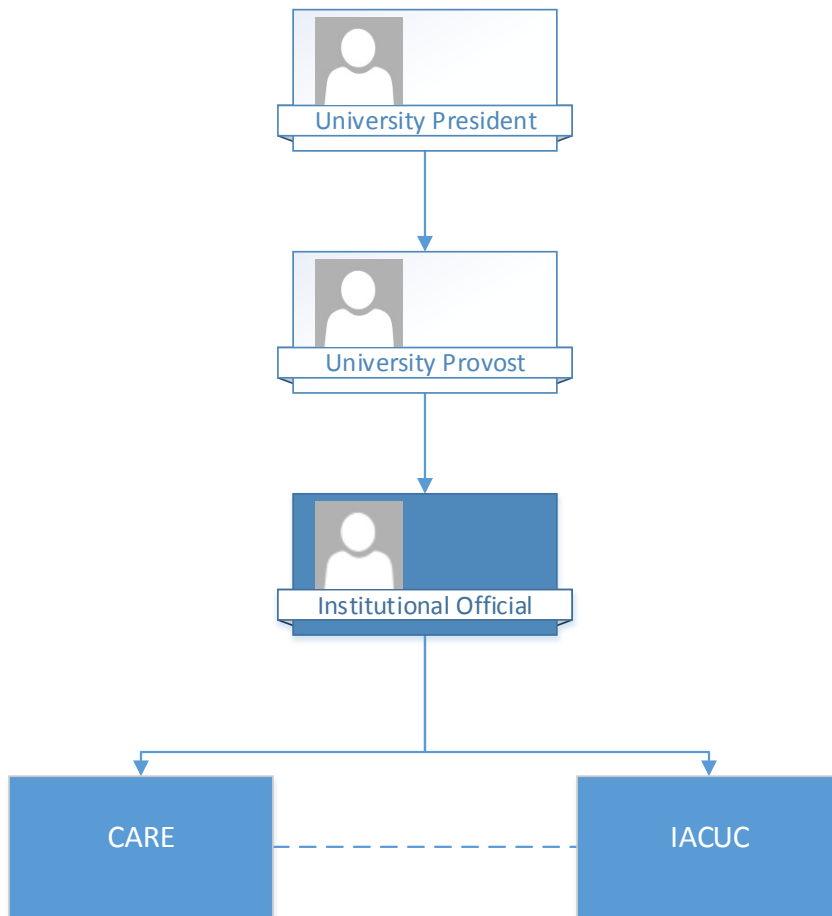
Any member of the university community who is aware of potential violations to this policy should report this concern, anonymously if so desired, to the Office of Research Integrity and Assurance, chair of the IACUC, or through the Cornell Hotline. No member of the university community bringing forth a legitimate concern will be discriminated against or be subject to any reprisal for reporting such violations. Individuals who take retaliatory action will be subject to discipline, up to and including discharge.

The identity of individuals providing information concerning possible violations, including fraud, will be protected within legal limits. Throughout the inquiry and investigation of alleged violation(s), all individuals who are involved in the complaint reporting and/or investigation process will take all reasonable precautions, consistent with the need for a complete and comprehensive review of the case, to maintain confidentiality and to protect the rights and legitimate interests of both the person making the disclosure of violation and the subject(s) of the investigation.

An investigation of the incident report, reporting and further actions will be taken in accordance with IACUC policies. Disciplinary measures may be taken if appropriate to the circumstances, by one of the following: immediate supervisor; department chair; college dean; relevant vice provost; responsible university office. After the investigation has concluded, at the request of a party to the complaint and if warranted by the circumstances, the chair, in concurrence with the IO, may release publicly a summary notice of the case, the issue, and the resolution.

APPENDIX A: LINES OF RESPONSIBILITY, ITHACA CAMPUS UNITS

Diagram 1
Lines of Responsibility



POLICY 1.4

Care and Use of Live Vertebrate Animals in Research and Teaching

INDEX

AAALAC	5, 19, 20, 23	Instruction	2, 21
Accreditation	5, 7, 8, 9, 10, 13, 17, 19, 20, 23	Management and operation	19
Anesthesia	7, 17	New animal facilities	17
AC (Animal Care).....	5, 10	New York, State of.....	3, 8, 13
Animal Care and Use Program.....	1, 2, 3, 4, 5, 7, 8, 9, 10, 13, 14, 15, 17	NIH.....	6, 8, 9
Animal Users Health and Safety Program.....	4, 5, 7, 16	Office of Research Integrity and Assurance .	1, 4, 6, 9, 23
Animal Welfare Act.....	3, 5, 8, 13, 19	OLAW.....	6, 8, 9
Animal Welfare Assurance	4, 5, 9	ORIA.....	6, 9, 18
APHIS	5, 10	Procurement, Animal	7, 16
AUHSP.....	3, 5, 16, 21	PHS	5, 6, 8, 9, 10, 13, 14, 22, 23
AV (attending veterinarian)	5, 9, 11, 14, 15, 23	Planning and design	20
AWAR.....	5, 8, 9, 10, 19, 23	Primates	18
Biosecurity	7, 16	Protocol	6, 7, 8, 9, 10, 11, 15, 16, 17, 19, 21, 22, 23
CARE	5, 7, 8, 9, 11, 14, 16, 17, 18, 19, 20	Preventive medicine.....	7, 16
Compliance	1, 5, 6, 8, 9, 10, 11, 13, 14, 20, 22	Principles	2, 3, 9, 13
Construction	8, 17, 18, 20	Procedures	2, 3, 9, 10, 14
Clinical disease.....	7, 16	Proposed animal activities	2, 22
Conflict of interest	3	Protocol	6, 7, 16
Cornell Center for Animal Resources and Education	1, 4, 13	Quarantine	7, 16
Disability	7, 16	Recordkeeping.....	23
Euthanasia	7	Recordkeeping.....	23
Environmental Health and Safety	4, 15	Reports	2, 23
Faculty	1, 5, 15, 16, 21	Reporting.....	5, 7, 8, 9, 10, 11, 19, 22, 23, 24
IACUC. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24		Review	7, 8, 11, 16, 19, 20, 22, 23, 24
Inspection	7, 10, 15	Senior vice provost for research.....	14, 16, 17, 18
Institutional Official	1, 2, 5, 10, 11, 14, 17	University policy	3
		USDA.....	3, 6, 8
		Violations.....	2, 4, 23
		Visitation	20