

DEPAUL UNIVERSITY



Research/Teaching/Exhibition Involving Vertebrate Animals or Fertile Eggs

Category: Academic Affairs - Operational

Responsible Department: Office of Research Services

Responsible Officer: Director of Research Compliance

Effective Date: 08/31/2018

Policy Summary

This policy covers: 1) the acquisition, care, and use of animals; 2) efforts to minimize animal pain, distress, and other harms to animals; 3) the training of personnel using animals; and 4) consideration of alternatives to animal use. It also mandates the establishment and maintenance of an Institutional Animal Care & Use Committee to review all animal facilities, research, and teaching protocols.

DePaul's Policy for the Use & Care of Vertebrate Animals was developed and is maintained by the Institutional Animal Care & Use Committee (IACUC) to be in accordance with federal regulations, law and agency guidance, as described below. To become effective, revisions to this policy must be approved by a majority of the voting members of the IACUC.

Scope

This policy affects the following groups of the University:

- Full-Time Staff
- Part-Time Staff
- Full-Time Faculty
- Part-Time Faculty
- Students

This policy affects:

- Members of the Institutional Animal Care & Use Committee
- Faculty, staff, and students using vertebrate animals and/or fertile eggs in research, in instruction, or for exhibition
- Faculty members in the sciences

- Office of Research Services staff

Policy

A. IACUC Statement of Purpose

The DePaul University IACUC is a federally-mandated research oversight committee charged with ensuring the proper care and humane treatment of vertebrate animals used in research and education. The use of animals in the laboratory and the classroom contributes to the quality of instruction and the advancement of scientific knowledge. The objective of the IACUC is to oversee the use of animals in pursuit of these goals, while requiring consideration of scientifically valid alternatives and refinements. The IACUC reviews all proposals for the use of vertebrate animals, inspects facilities, and ensures that animal research and teaching activities are in compliance with federal regulations, legal statutes, and ethical guidelines. The IACUC provides assistance and training to investigators, students, and staff who work with animals, fulfilling DePaul's obligation to advance knowledge and educate our students while meeting the highest standards of scientific rigor and humane care.

B. IACUC History

The Animal Welfare Act (AWA) was first passed in 1966 to address the concerns of the American public regarding the acquisition and use of animals in research. To ensure adherence to the AWA, the Congress established self-oversight mechanisms for all research institutions; this oversight is through the IACUC. The 1985 amendments to the AWA and concurrent changes in Public Health Service Policy on the Human Care and Use of Laboratory Animals (PHS Policy) increased the oversight policy for IACUCs. Today every institution conducting vertebrate animal-based research, teaching, or testing, must establish an IACUC to oversee the institution's animal care and use program. The IACUC's membership and responsibilities are mandated and defined by federal regulations and laws and are carried out through local policy. The Committee carries the mandate of the federal regulations and laws for the IACUC to be the final authority with regard to the welfare of animals used by the institution.

Biological research at DePaul University employs animals in a number of contexts from investigation of disease processes affecting both humans and animals, to normal functions of humans and animals, to animal use for teaching purposes, to studies of human and animal involvement in the ecosystem in general. The advancement of biological and medical knowledge is inextricably coupled with animal research; quite simply, most of what we know in all facets of biology and medicine is derived directly or indirectly from research involving animals. Similarly, preparation of graduate and medical students requires some degree of animal contact. Consequently, the involvement of animals in research and teaching cannot be avoided if DePaul continues to perform its mission and responsibilities to society.

The use of animals in research and teaching imposes moral, scientific, and legal obligations for their humane care and treatment. The Policy for the Use and Care of Vertebrate Animals has been prepared to provide DePaul research faculty, staff, and students with information pertaining to these obligations. This policy contains essential information for investigators regarding applicable regulations and policies, training requirements, and protocol preparation. It also provides basic information about laboratory animal care and veterinary programs at DePaul.

The information contained within this policy has been amalgamated from many sources. The policy contains information regarding the federal regulations, which impact animal use and local policies established by the IACUC to implement the committee's mandated oversight responsibilities. Every effort has been made to provide accurate and up-to-date information; if errors are noted, please notify the Director of Research Compliance at 312-362-7593.

C. The Ethics & History of Research Involving Non-Human Vertebrates

A discussion of the ethics and history of research using non-human vertebrates is available on the IACUC webpage at [this link](#)

D. Governing Federal Regulations & Policies

1. The Animal Welfare Act: The AWA was first enacted in 1966 and was amended in 1970, 1976, 1985, and 1990. Additional minor revisions to the Act continued to be made throughout the 1990's and 2000's. For a complete annotated summary of revisions to the act go to: <http://www.nal.usda.gov/awic/pubs/AWA2007/awa.shtml>. This act of Congress regulates the transportation, purchase, care, and treatment of animals used in research, for exhibition, and sold as pets. The AWA specifically defines "animals" as dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, and other warm blooded animals intended for use in research. The AWA does not cover farm animals or laboratory bred rats and mice. However, these species are covered by PHS Policy.

Recent amendments to the AWA address such issues as exercise for dogs, psychological well-being of primates, the composition, and duties of the IACUC, responsibilities of the attending veterinarian, and training of personnel using animals in experimentation. The AWA specifies that research facilities must:

- Consider procedures to minimize pain and distress; Consider the use of alternative animal models and/or research methods;
- Require veterinary consultation for use of anesthetics and for pre and post surgical care;
- Prohibit the use of paralytics without anesthesia;
- Restrict the use of animals in more than one operative procedure unless scientifically justified;
- Provide training for individuals working with animals; and
- Establish an Institutional Animal Care and Use Committee.

The Act also requires the IACUC to review all protocols using animals to ensure they meet criteria listed in the amendments to the Act, and to conduct semiannual inspections of all animal facilities and areas where animals are used. This includes randomly selected research and student laboratories.

The AWA is administered by the United States Department of Agriculture (USDA). Research facilities are subject to unannounced inspections by USDA veterinarians. The IACUC is required to file an annual report listing the species and numbers of animals used in research, instruction, and exhibition.

2. Public Health Service Policy: The PHS Policy for Humane Care and Use of Laboratory Animals requires each institution which receives PHS funds for research involving animals to file an Animal Welfare Assurance statement with the Office of Laboratory Animal Welfare (OLAW) in the National Institutes of Health (NIH). This statement commits the institution to compliance with the AWA, the NIH Guide for the Care and Use of Laboratory Animals (NIH Guide), the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, and other applicable laws and regulations. The Assurance must describe in detail the institution's program for the care and use of animals (all vertebrate species, including rats and mice) and its program for assuring compliance with PHS Policy.

PHS Policy requires IACUCs to approve the care and use of animals proposed in PHS grant applications before funds will be awarded. IACUCs also are required to conduct semiannual assessments of the institution's animal care and use program, using the NIH Guide as a basis for evaluation. If significant deficiencies in the institution's program are identified, the institution must correct the deficiencies and report both the deficiencies and how they were corrected or the plan for correction (including the time frame for completion) in the semiannual reports.

An institution's failure to comply with these policies may lead to various penalties, including the termination of PHS support for all projects involving animals.

3. U.S. Government Principles for the Utilization & Care of Vertebrate Animals Used in Research, Testing, & Training: The following principles were developed by the U.S. Government's Interagency Research Animal Committee. Both PHS Policy and institutional policy require that all use of animals in research, teaching and exhibition at DePaul University conform to these principles, which are reproduced below:

I. The transportation, care and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable federal regulations, laws, guidelines and policies.

II. 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.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered before live animals are used.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound specific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or

anesthesia. Surgical or other painful procedures should not be performed on anaesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of procedures, or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally the housing, feeding, and care of all animals used in biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided, as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals and species-specific training.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as the IACUC. Such exceptions should not be made solely for the purposes of teaching or demonstration.

E. DePaul's Assurance of Compliance with PHS Policy

On July 11, 2001, DePaul University entered into a contract (called an Animal Welfare Assurance) with the federal Office of Laboratory Animal Welfare assuring that DePaul University is in compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals.

1. **Applicability:** DePaul's Assurance is applicable to all research, research training, experimentation, biological testing, and related activities (here after referred to as "activities"), involving live, vertebrate animals supported by the PHS and conducted at DePaul or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or PHS-supported activity by this institution.

As a Category 2 institution under PHS Policy, all of DePaul's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1 and 2 of PHS Policy, and reports prepared in accordance with IV.B.3 of PHS Policy. Semi-annual reports of the IACUC evaluations are submitted to OLAW as appropriate.

2. **Institutional Policy:** This institution will comply with all applicable provisions of the Animal Welfare Act and other federal statutes and regulations relating to animals. This institution is guided by the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by the Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

This institution has established and will maintain a program for activities involving animals in accordance with the NIH Guide.

3. Institutional Animal Care & Use Committee: The institution has established an IACUC, which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. PHS Policy and Animal Welfare Regulations (AWR) stipulate that the IACUC consist of at least five voting members, including:

- a veterinarian with training and/or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution;
- a practicing scientist with experience in animal research;
- a member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy); and
- an individual who is unaffiliated with the DePaul in any way other than as a member of the IACUC and who is not a member of the immediate family of anyone affiliated with DePaul.

An individual who meets the requirements of more than one of the PHS categories may fulfill more than one requirement. Because of the specificity of expertise required for IACUC membership, voting members are appointed for indefinite terms and are encouraged to serve for at least three years.

The IACUC also includes 5 non-voting, ex-officio members. The ex-officio members are the Associate Vice President of Academic Affairs-Faculty Development, the Director of the Research Support Facility, the Director of Research Compliance, and the Research Protections Assistant from the Office of Research Services.

In accordance with the Health Research Extension Act of 1985, IACUC members are appointed by DePaul's President, on the recommendation of a subcommittee of the IACUC. This appointment subcommittee is made up of the IACUC Chair, the Director of Research Compliance, and the Associate Vice President for Academic Affairs-Faculty Development. The subcommittee makes its recommendations to the President, after considering nominations from department chairs, IACUC members, Faculty Council, and researchers.

Current IACUC membership, a summary of the administrative oversight of the IACUC and the Research Support Facility, and contact information are available on the IACUC webpage at [this link](#)

4. Functions of the IACUC under PHS Policy: The IACUC will:

- Review at least once every six months the institution's program for humane care and use of animals, using the NIH Guide as a basis for evaluation;
- Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the NIH Guide as a basis for evaluation;
- Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.1 and 2 and submit the reports to the Provost, who serves as the Institutional Official;
 - o The reports are updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request.
 - o The reports contain a description of the nature and extent of the institution's adherence to the NIH [Guide](#) and PHS Policy and identify specifically any departures from the provisions of the NIH Guide and PHS Policy, and state the reasons for each departure.
 - o The reports distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with PHS Policy, and, in the judgment of the IACUC and the Provost, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.
- Review concerns involving the care and use of animals at the institution;
- Make recommendations to the Provost regarding any aspect of the institution's animal program, facilities, or personnel training;
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities;
- Be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of the PHS Policy.

5. Review of Project Renewals: PHS and USDA differ in their requirements for the renewal of approved protocols. PHS requires application renewal at least once every 3 years, whereas USDA requires it annually. While USDA's exclusion of rats, mice, and birds allows for dual mechanisms of IACUC monitoring activities involving USDA-covered species annually and activities involving all other species triennially, many institutions have chosen to establish uniform procedures that satisfy both of these federal requirements.

The DePaul IACUC will conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC (generally, once per year). In addition, the IACUC will conduct a complete review in accordance with IV.C.1-4 of PHS Policy at least once every three years.

F. DePaul University's Training Program for Work with Animals: Under DePaul's Animal Welfare Assurance with the Office of Laboratory Animal Welfare, the university assumed responsibility for assuring that all scientists, animal technicians, and other personnel involved in animal care, treatment, and use were provided with appropriate training and/or instruction. The IACUC has since developed guidelines to ensure that individuals are properly trained and that this

training is appropriately documented and placed on file. The training of individuals working with laboratory animals should fulfill the following two objectives:

- training or instruction in the humane practice of animal care and use
- training or instruction in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress

The following types of training are required for all individuals working with animals as described in the Procedures section below:

- General Laboratory Training;
- Species/Laboratory-Specific Training; and
- Occupational Health & Safety Training.

G. Animal Husbandry & Veterinary Care: This section describes the function and services of the Research Support Facility and provides basic information about animal husbandry, veterinary care, animal surgery, and euthanasia.

1. Animal Housing & Care: The Research Support Facility is responsible for managing laboratory animal care in compliance with the federal Animal Welfare Act, the NIH Guide, the PHS Policy on Humane Care and Use of Laboratory Animals, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. The Director of the Research Support Facility reports to the IACUC. The functions of the Research Support Facility are daily animal care and monitoring.

The Research Support Facility contains 5 animal rooms (40 sq. ft. each) and a quarantine room. Access is electronically restricted by a card-swipe system. All animal holding rooms have at least 15 changes of air per hour and are controlled for temperature, humidity, and light-dark cycle. Environmental monitoring is provided by portable sensors in each room. The facility also features a separate surgical suite comprising two prep rooms and a surgery room with a portable biosafety cabinet. Dedicated cleaning facilities include a Steris cage-washer (>180 degrees Fahrenheit) with appliances for processing cages, trays, and water bottles. Species previously housed in the facility include mice, rats, fish, turtles, and frogs.

The Research Support Facility should provide housing and care for vertebrates at DePaul University used for research, teaching, and/or exhibition purposes. On a semiannual basis, all lab animals are tested for diseases relevant to each species in order to protect the animals as well as animal personnel. At the present time no per diem rates for DePaul investigators using animals are being assessed, costs being the responsibility of the investigator.

Routine preventative medicine and consultation on animal selection and use are the responsibility of the investigator, as are animal research services such as injections, blood collection, and surgical/anesthetic services. The IACUC personnel reserves the right to ascertain that protocols are being followed and animal care is appropriate. Animals may not be housed in research laboratories for periods longer than 24 hours without prior approval from the IACUC.

2. Animal Husbandry: The consulting veterinarian is available to assist researchers with project-specific animal husbandry concerns.
 - a. Caging: The Research Support Facility is responsible for approval of appropriate cages for laboratory animals, and for ensuring that housing conforms to USDA and NIH Guide standards while meeting research needs. The investigator is also responsible for maintaining cages in good repair. Exceptions to standards must be justified on the basis of experimental or species requirements. Investigators who require special housing may contact the Director of the Research Support Facility to discuss their needs.
 - b. Environmental Factors
 - i. Temperature & Humidity: The NIH Guide has defined requirements for the proper maintenance of laboratory animals. Environmental factors such as temperature and humidity must be carefully monitored because they affect metabolism and behavior; improper temperature and humidity levels may adversely affect research results. There is a marked difference in temperatures recommended for various species. The Facility monitors and maintains appropriate temperature and humidity for all housed animals. Temperature logs are housed in the facility. The appropriate recommended relative humidity and temperature for commonly used laboratory animals can be found in Appendix A along with physiological data for each species that may be of use to investigators.
 - ii. Micro- and macro- environments: The design of cage or primary enclosure can greatly influence the animal's environment. The environment in the cage (the microenvironment) may differ from the environment of the animal room (the macro environment). Some of the newer caging systems for rodents, for example, incorporate a microbiological barrier. This may result in substantially higher temperature, humidity, carbon dioxide, and ammonia in the cage than in the room. Since such factors may adversely affect research as well as animal health, they should be carefully considered in experimental design and animal housing.
 - iii. Ventilation: The long-accepted ventilation guideline of 10-15 room air changes per hour is based on the observation that this figure provides sufficient ventilation to keep odors below objectionable levels. Heating, ventilation, and air conditioning (HVAC) systems in animal facilities require constant monitoring to assure proper ventilation and appropriate temperature and humidity levels. Any departures from appropriate levels should be reported to the Research Support Facility Director as soon as possible. Facility problems noted after working hours should be reported to Facilities Operations. The investigator should work with Facility Director and Facilities Operations to ensure that environmental control systems in animal facilities function properly.
 - iv. Illumination: The lighting in an animal room must meet several needs. It must meet the animals' biological needs with regard to quality and periodicity, and must also provide adequate illumination for daily observation and care of the animals. In addition, lighting should be sufficient to ensure safe working conditions for animal

care personnel.

The Research Support Facility provides timed light controls in animal housing areas. Other light cycles can be arranged through consultation with the Research Support Facility.

c. Feed: Standardized commercial diets are available for most laboratory species. The investigator is responsible for providing appropriate diets and for ensuring that food is fresh and free from contaminants. Dried food should not be kept more than six months after the milling date. All expired diets should be discarded.

For special research needs, certified diets that have been assayed for commonly encountered environmental contaminants may be necessary.

d. Bedding: Wood shavings or chips are the standard bedding materials for rodents approved by Research Support Facility. It has been documented that aromatic hydrocarbons from pine shavings or cedar bedding can induce production of hepatic microsomal enzymes. Accordingly, such bedding may be inappropriate for animals involved in certain kinds of experiments. The Research Support Facility can assist with special bedding needs.

e. Sanitation

i. Cleanliness: The Animal Welfare Act and the NIH Guide have established schedules for the frequency of cleaning animal rooms and for changing cages. In some cases frequent cage cleaning may be disruptive to research objectives, as in the case of reproductive studies where frequent changes may eliminate pheromones necessary for reproduction. Adding a small portion of bedding from the soiled cage to the fresh cage may prevent such problems while maintaining sanitation. Schedules can be altered to accommodate special research needs by written arrangement with the Research Support Facility. Significant deviation from standard sanitation schedules and practices requires approval by the IACUC. Documentation of cage cleaning is necessary.

ii. Waste Disposal: Radioactive or biohazardous carcasses and animal wastes must be disposed of according to procedures established by the Radiation Safety and Biosafety Committees respectively. All other animal carcasses and animal wastes are disposed of by the Research Support Facility. A freezer has been designated by the Research Support Facility for the deposit of animal carcasses. The carcasses are periodically removed by Research Support Facility personnel and disposed of in accordance with code requirements. No food should be placed in this freezer.

iii. Vermin Control: The presence of pests in animal colonies can result in contamination of feed and bedding, and the introduction of disease. The Research Support Facility is responsible for the pest control program in the animal facilities. Pesticides are used in animal areas only when necessary, and then only after consultation with the investigator(s) whose animals will be exposed to them.

3. Veterinary Care: The consulting veterinarian provides a program of veterinary care through institutional support. This may include: daily assessment of animal health, prevention, control, diagnosis, and treatment of animal disease and injury; consultation with researchers on handling, restraint, anesthesia, analgesia, and euthanasia; training of research personnel in appropriate surgical techniques and procedures; and monitoring of surgical procedures and postoperative care. Adequate veterinary care is an essential part of every animal care program. The AWA states that each research facility should have an attending veterinarian who should provide effective care in the above stated responsibilities.

a. Animal Well-Being: According to federal law and regulations and as designated by DePaul, the attending veterinarians have the authority and responsibility for making determinations concerning animal well-being and assuring that animal well-being is adequately monitored and promoted. They have the authority to remove an animal from an experiment which is adversely affecting its well-being beyond the level approved by the IACUC. Animal well-being includes both the physical and psychological aspects of animal's condition evaluated in terms of environmental comfort and freedom from pain and distress and appropriate social interactions. Procedures that will cause more than momentary pain must be performed with appropriate sedatives or analgesics, unless withholding such agents is justified by scientific reasons and provided to the IACUC in writing and approved by the IACUC. Procedures that would likely cause more than momentary pain to humans should be considered a painful procedure for that animal and pain/distress intervention provided or a scientific justification provided indicating why pain relieving agents cannot be given.

i. Pain, Stress and Distress: Freedom from pain and distress is important to the well-being of an animal. Evidence of any or all of these is important to evaluation of well-being.

- What is Pain?

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain may be divided into several different categories based on the location of the source of the pain, including

- o Somatic pain (originating from skin, muscles, joints, tendons, or bones)
- o Visceral pain (originating for internal organs)
- o Neuropathic pain (originating from damaged nerves)

It is important to note that animals feel pain to the same extent (pain detection threshold) as humans; however, their tolerance to it may vary with the species and individual. The rule of thumb for those who use animals is: If the procedure can be expected to cause pain in humans, you must assume it will cause pain in animals.

- What is Stress?

Stress is the effect produced by external (physical or environmental) or internal (physiological or psychological) factors that induce the alteration in an animal's homeostatic or adaptive state. An animal's response to stress is to attempt to adapt. It is important to note that stress is not necessarily bad if an animal can adapt. For example, the shipment of animals to a new facility is a stressor; however, allowing the animal to rest 2-3 days prior to use in an experiment allows the animal to adapt to its new environment.

- What is Distress?

Distress, on the other hand, is always unhealthful and may be caused by unrelieved pain, anxiety, fear, social deprivation, and boredom. Inappropriate husbandry and experimental design also can lead to maladaptive behavior and distress.

ii. Specific Ethical & Legal Obligations: Our ethical obligations overlap with our legal obligations for the recognition of pain, stress, or distress and for provision of relief. Legality, however, is not the same as morality, and it is often the case that legality sets merely the bare minimum level of demands. The charge is thus not simply to follow the letter of the current law, but to maintain the highest moral standards as well when dealing with animals.

- Procedures must avoid or minimize distress and pain. The principal investigator must consider alternatives to procedures that might cause more than momentary pain or distress.
- Appropriate sedation, analgesia, or anesthesia must be used for procedures that can cause more than momentary pain or distress, unless scientifically justified and approved the IACUC.
- Potentially painful or distressful procedures must be planned in consultation with the attending veterinarian and approved by the IACUC.
- Euthanasia must be performed if an animal experiences severe or chronic pain or distress that cannot be relieved.

b. Preventive Medicine

i. Animal Procurement: Newly acquired animals can introduce disease into established colonies. In addition, production colonies maintained by suppliers occasionally experience outbreaks of disease. Daily observation by personnel qualified to verify animal's well-being is required. Investigators are required to monitor animal health quality from their suppliers and maintain quality control data provided by vendors. This information should be provided to the Director of the Research Support Facility for record purposes and to assist investigators in choosing appropriate sources of animals.

To minimize the possibility of introducing disease into the DePaul animal facility, all arrangements for acquiring and housing live vertebrates must be made through the Director of the Research Support Facility. This includes transfer of animals from other institutions, or between rooms within the quarters. Animals may not be purchased or otherwise acquired until a fully approved animal use protocol is on

file. The investigator is responsible for determining if permits (such as U.S. Fish and Wildlife or Illinois Fish and Game) are required and any necessary federal or state permits must be obtained before animals are acquired. The Director of the Research Support Facility may be able to assist investigators in determining when permits are needed and in obtaining them.

ii. Quarantine and Stabilization: With some species of laboratory animals, quarantine is necessary to minimize the introduction of disease into established colonies. The extent of the quarantine period is determined by the species and by knowledge of the animal's source and previous history. Arriving animals, regardless of source, should be allowed a 5 day stabilization period before use. Such a period allows the animal to recover from shipping stress, adapt to its new surroundings, and become physiologically stable. Terminal procedures do not usually require a stabilization period from a humane care and use standpoint, but may from a scientific point of view.

iii. Separation of Species: Physical separation of animals by species is generally recommended to reduce the possibility of transmission of latent diseases. This separation is usually accomplished by housing different species in different rooms. Animals of the same species which are obtained from multiple sources may differ in their microbiological status, in which case housing in separate rooms is advisable, but may not be practical due to facility constraints.

c. Surveillance, Diagnosis, Treatment and Control of Disease: Personnel should report any signs of illness, injury, or abnormal behavior to the principal investigator and the Director of the Research Support Facility.

d. Emergency Care: Any health problem noted by any animal user at any time must be reported to the researcher, the Director of the Research Support Facility, or the consulting veterinarian in a timely fashion. The Research Support Facility staff should also be informed in a timely way of facilities malfunctions (e.g., excessively hot or cold animal rooms) which appear to directly threaten animal health. Note that emergency phone numbers are posted near all telephones in the facility.

e. Anesthesia and Analgesia: As previously stated, it is our ethical and legal obligation to avoid or minimize distress and pain. If any or all of these cannot be avoided, appropriate means must be used for procedures that cause more than momentary pain or distress. These interventions may be a pharmacologic intervention (pain and pain-induced stress) or they may be nonpharmacologic (distress not induced by pain). Types of drugs used to control pain and distress include anesthetics, analgesics, and tranquilizers/sedatives.

- General anesthetics are drugs that produce unconsciousness, analgesia, and muscle relaxation sufficient to enable the procedures to be performed painlessly. They may be injected into an animal or inhaled by the animal for effect. Combinations of drugs may be used together to create an appropriate level of anesthesia. Anesthesia must be monitored to ensure an adequate depth of anesthesia. Commonly monitored parameters include eye and knee

reflexes, deep pain response (applying pressure to a digit and monitoring animal's response to it), body temperature, heart rate, mucous membrane color, respiratory rate, and pulse. Anesthetic overdose may be indicated by slow, weak pulse, absence of breathing, decreased blood pressure, irregular heart rate, pale mucous membrane color. When an anesthetic emergency does occur, supplying and ventilating the animal with oxygen, administering fluids, and warming the animal are all useful. Some anesthetics have reversal agents and would also be recommended to be given if appropriate.

- Analgesics are substances that alleviate pain without causing loss of consciousness so are commonly used when a procedure is considered painful. The categories include opioid and nonopioids. The choice will vary with type of pain the procedure has the potential to induce, the species of animal, age, duration of action needed, and research considerations.
- Tranquilizers and sedatives are substances that reduce anxiety and stress in an animal that may experience such when handled. It is important to note that few (xylazine and detomidine are exceptions) have analgesic (pain relief) properties. Tranquilizers and sedatives include acepromazine, benzodiazepines, and thiazine derivatives. They are used for chemical restraint and as preanesthetic agents.

Animal procedures are reviewed by the IACUC to ensure that proposed anesthetics and analgesics are appropriate for the species and research objectives. The consulting veterinarian is available to provide assistance with, or training in the proper administration and use of anesthetics. A list of approved anesthetics and analgesics is provided in Appendix B. Other drugs may be approved by the IACUC after consultation with the veterinarian has been made.

Institutional policy requires written documentation of all survival surgical procedures, and the types and amounts of anesthetic, analgesic or tranquilizer drugs used. This documentation should be maintained in or near the animal procedure area, and is subject to inspection by USDA veterinary inspectors and the IACUC during semiannual inspections of the Research Support Facility and other animal study areas. All manipulations and drug use in animals should be recorded.

The NIH Guide requires that any proposal to conduct painful procedures without anesthesia or analgesia must be approved by the IACUC. Such procedures must be supervised directly by the responsible investigator.

f. **Surgery and Postoperative Care:** Animal surgery may only be performed by personnel adequately supervised or trained and competent in the procedure described in the approved protocol. PHS Policy and AWA place responsibility with IACUC to determine whether personnel are qualified.

i. **Survival Surgery:** Survival surgery is defined as any surgery from which the animal recovers consciousness. Major surgery is defined as any surgical intervention that penetrates a body cavity or has the potential for producing a permanent handicap in an animal that is expected to recover. Minor surgery is any operative procedure in

which only skin or mucous membrane is incised (e.g., implanting pumps in subcutaneous tissue).

However, if a minor surgical procedure has a great risk of infection it will be treated as a major surgery (e.g. a vascular cutdown for chronic catheter placement is considered a major procedure). Multiple major survival surgery is defined as two or more major survival surgical procedures on a single animal. It is permitted by the IACUC only under special circumstances, such as when surgeries are essential and related components of a single study. Cost alone is not an adequate reason for performing multiple survival surgeries on an animal.

Surgical procedures on mammals other than rodents must be conducted in surgical facilities intended for that purpose, using aseptic techniques. These techniques include wearing sterile surgical gloves, gowns, caps, and face masks; using sterile supplies and instruments; and maintaining an aseptically prepared surgical field.

Minor surgical procedures may be performed in a suitably located and equipped laboratory area, subject to approval by IACUC. Appropriate aseptic techniques for these procedures includes a clean uncluttered work area, preparation of the surgical site including clipping of the hair, disinfection of the skin and draping of the surgical site with sterile drapes; the use of sterile supplies and instruments; and the use of sterile gloves and surgical mask by the surgeon and any assistants working in the surgical field.

ii. Pre- and post-operative care: Animals should generally be fasted overnight prior to anesthesia and surgery to prevent vomiting, aspiration, and problems associated with a distended intestinal tract. The animal should be allowed access to water until several hours (2-3) before surgery. Since these generalizations do not apply to all species, contact the consulting veterinarian if there is any doubt when planning a procedure.

Postoperative care should include observation of the animal to ensure uneventful recovery from anesthesia and surgery. The animal may be returned to its cage; however, no food or water should be left in the cage until the animal is fully conscious. The animal must be monitored until it regains sternal recumbency and is capable of holding its head up. The animal should be kept warm and dry and administered fluids, analgesics, and antibiotics as determined by the consulting veterinarian. Surgical wounds should be kept clean, and bandages or wound dressings changed as frequently as necessary to keep them clean and dry.

Subsequent care may include supportive fluids, analgesics and other drugs as required, monitoring of the animal to include daily body temperature, clinical observations for signs of pain, abnormal behavior, appetite, and excretory functions, providing adequate care of surgical incisions and maintaining appropriate medical records. If there are any questions about postoperative care, contact the consulting veterinarian.

CAUTION: Use of heat lamps and electric heating pads can result in severe burns or hyperthermia in animals that are anesthetized or otherwise unable to escape from the

heat. Close observation is required, and use of circulating water blankets is recommended whenever possible.

iii. Non-survival surgery: Non-survival surgery is defined as any surgery in which the animal will not regain consciousness after being anesthetized. Such procedures may be performed in a suitably located and equipped laboratory with IACUC approval.

g. Euthanasia for Common Lab Animals: The NIH Guide defines euthanasia as "the procedure of killing animals rapidly and painlessly." Institutional euthanasia guidelines follow those established by the American Veterinary Medical Association's Panel on Euthanasia (provided on the Office of Research Services web site). Proposed euthanasia techniques must be reviewed and approved by the IACUC.

h. Euthanasia of Fertile Reptile and Avian Eggs and Hatchlings: The PHS Policy on Humane Care and Use of Laboratory Animals requires that each Institutional Animal Care and Use Committee review projects involving live vertebrate animals. PHS Policy does not cover fertile vertebrate eggs that have not hatched. However, DePaul University has developed institutional requirements for the use of fertile reptile/avian eggs.

In the event that a fertile reptile/avian egg that is being used in research or teaching hatches, the IACUC will require that the researcher/instructor refer to the 2000 Report of the American Veterinary Medical Association Panel on Euthanasia for the appropriate species-specific selection of anesthesia and euthanasia. The researcher/instructor is responsible for considering the stage of development of embryos and whether or not the embryos have developed sensitivity to pain. For the developing chick embryo, for example, the following procedure would be recommended:

- Fertile eggs of less than 10 days' incubation should be removed from the incubator and allowed to cool to room temperature for 2 hours, after which they should be chilled at 4 degrees C overnight. Chilled eggs should be frozen at -20 degrees C to ensure death.
- For eggs incubated 10 days or more but less than 18 days, the recommended procedure of euthanasia would be to decapitate the embryo in the high cervical region with heavy shears after piercing the eggshell.
- For eggs incubated past day 18 but not yet hatched the recommended procedure of euthanasia would be to gas the eggs with CO₂ followed by decapitation of the embryo in the high cervical region with heavy shears after piercing the eggshell with heavy shears.

i. Drugs and Other Medications

i. Controlled Drugs: Controlled drugs for use in animal studies may be ordered through a pharmacy. Narcotics which have to be ordered require a longer lead time than uncontrolled drugs. Each investigator is responsible for acquiring a DEA license and will have to sign for release of these controlled substances. The Federal Drug Enforcement Agency requires that all controlled substances be stored in a secure locked cabinet and that an aliquot log be maintained by the user accounting for the entire volume of each drug received. The log is provided by the pharmacy when the substance

is received. This log must be returned to the pharmacy before a second bottle can be issued. The following information must be provided for each bottle of drug received:

- Name, form or composition, quantity, and concentration of drug
- Date and volume of each aliquot dispensed
- Name of person dispensing drug and purpose for which dispensed
- Reference to data books showing which animals and number treated should be included if possible.

Outdated or unused controlled substances should be disposed of appropriately.

ii. Non-Controlled Drugs and Medical supplies: Non-controlled drugs and other animal study-related items such as drugs and surgical supplies are the responsibility of the principal investigator. Copies of purchase orders should be provided to the Director of the Research Support Facility.

Procedures

A. Researcher Rights and Responsibilities

1. Protocol Submission

a. Activities that Require Approval: Any research, exhibit, or instructional use of vertebrates by faculty, students, or staff requires the submission of an animal use protocol to the IACUC for review. Animal use protocols must be fully approved before an animal user may acquire, house, or use animals. Copies of the protocol form and samples of approved protocols may be obtained by contacting the Office for Research Protections.

The use of fertile eggs or invertebrates does not require submission of a protocol, but researchers are required to notify the IACUC by contacting the Office for Research Protections at least two weeks prior to beginning the work. Similarly, individuals intending to exhibit animals must notify the Office for Research Protections at least two weeks prior to the exhibit and may be required to provide an exhibitor's license or other additional documentation.

b. Information Required in the Protocol: The protocol form must include a non-technical explanation of the research, a justification for the use of animals, a description of all procedures to be performed on animals, and an explanation of precautions to be taken to guarantee humane care and treatment of animals. Specifically, researchers are advised to ensure that proposed research activity and its accompanying protocol meet the following requirements/guidelines:

- The living conditions of animals will be appropriate for their species and will contribute to their health and comfort;
- The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being maintained or studied;

- Medical care for animals will be available and provided as necessary by a qualified veterinarian;
- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;
- The protocol provides a rationale for the use of animals, the selection of each species, and the number of animals to be used for each species;
- The protocol includes a complete description of the proposed animal use and the significance of the work;
- The protocol provides a written assurance that the activities do not unnecessarily duplicate previous experiments;
- The protocol documents consideration of alternatives to painful procedures and provides a written narrative description of the methods and sources used to determine that alternatives were not available;
- The protocol includes a description of the procedures and drugs used to provide relief from pain or distress; and
- A protocol provides a description of any euthanasia method to be used, and methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator and approved by the IACUC.

Investigators with questions regarding protocol preparation are encouraged to contact the IACUC Chair or the Director of the Research Support Facility. Thorough preparation of protocols facilitates the review process and reduces the chance of delay in initiating projects and in review of applications by extramural funding agencies. Protocol approval must be renewed annually.

c. Timetable for Submission

- i. Applications Funded by National Institutes of Health (NIH) or National Science Foundation (NSF): Both NIH and NSF require verification that an applicant awarded funds for animal research has an approved animal use protocol for the proposed project before being issued the funds. When submitting applications for NIH or NSF funding of animal research, researchers must notify the Office of Research Services that a proposal for funding has been submitted, but are not required to submit a protocol to the IACUC for review until the grant is awarded. Researchers should consult with the Office of Research Services to determine timelines for grant submission and IACUC review.
 - ii. Other Research and Teaching Protocols: All other protocols must be submitted at least two weeks prior to the next meeting of the IACUC. Because protocols frequently require revisions before receiving IACUC approval and because resubmissions will not be considered until the next IACUC meeting, investigators are advised to submit protocols with sufficient lead time. Generally, the IACUC meets monthly from September through June and when needed in August, and summaries of protocol reviews will be issued by the IACUC within one week of the date of the review.
- d. Protocol Monitoring & Annual Renewal: All approved protocols must be submitted to the IACUC for renewal annually after the initial approval is obtained. The researcher

must submit a Protocol Renewal Form, which documents any modifications to the protocol approved since the last review and reports progress over the previous year. Although an annual reminder will be sent to researchers about submitting a renewal form, it is the responsibility of the researcher to submit renewal materials within the timeframe provided on the reminder and with sufficient time to allow for review of the protocol by the IACUC prior to the anniversary of its initial approval. Failure to submit renewal materials in a timely fashion will result in the expiration of the protocol's approval, will require that all research activities on that project stop until re-approval is obtained, and, in some instances, will necessitate that the review process is reinitiated by submitting materials afresh for IACUC review.

In addition, every three years a new protocol application for each ongoing project must be submitted for IACUC review. Although an expiration notice for each protocol will be sent to researchers two months in advance of the anniversary of initial approval, it is the responsibility of the researcher to inform the IACUC that the project will end prior to the expiration date or to submit a new protocol application within the timeframe provided on the reminder and with sufficient time to allow for IACUC review prior to the anniversary date. The protocol application will be reviewed under the same procedures as new protocols that have never received approval.

2. **Appeal of IACUC Decisions:** If the IACUC determines that the requirements of PHS Policy and the AWA have not been adequately addressed and accordingly disapproves a protocol or suspends an activity, the Principal Investigator may appeal the decision in writing or may request an appearance before the IACUC to address the IACUC's concerns. During the first appeal, the researcher may be asked to describe and/or demonstrate the procedures used in the research.

If the IACUC's concerns remain unresolved, the researcher may request a meeting with the IACUC in order to present expert witnesses to testify to the adequacy, appropriateness, and/or necessity of the procedures outlined in the proposal. The decision of the Committee following the second appeal is final, as the federal regulations do not allow another agent of DePaul to administratively overrule an IACUC decision.

3. **Animal Acquisition, Housing, & Care**
 - a. **Arrangements for Acquisition and Housing:** All arrangements for acquiring and housing live vertebrates from any source must be made through the Research Support Facility. Arrangements for housing must be made before an order will be placed. Animals may not be purchased or otherwise acquired until a fully approved protocol is on file. In many cases, arrangements will need to be made for quarantine, at the discretion of the Research Support Facility before animals are ordered. The investigator is responsible for determining if permits (such as U.S. Fish and Wildlife or Illinois Fish and Game) are required and any necessary permits must be obtained before animals are acquired. The Research Support Facility or the IACUC may be able to provide advice on this matter. For additional information about acquisition and housing of animals, see the NIH Guide.

Users requiring special care, equipment, or supplies for their animals or exemptions from standard animal care procedures should inform the Director of the Research Support Facility. These special needs should be detailed on the IACUC protocol. Researchers who will use materials or procedures that may be hazardous to personnel must notify the IACUC, as well as the Research Support Facility Director. As importantly, researchers who will use infectious materials or recombinant DNA may be required to submit protocols to the Institutional Biosafety Committee (IBC) and must contact the IBC Chair to ensure that all obligations to the IBC are fulfilled. Finally, when radioactive materials or biohazardous agents or materials will be used, researchers must contact the Radiation Safety Officer and/or the Office of Risk Management and Environmental Health and Safety to determine whether there are any additional institutional requirements.

b. **Animal Identification and Record Keeping:** The AWA and the NIH Guide require appropriate identification of animals and maintenance of animal records. Accepted methods of animal identification include room, rack, and cage cards, collars and bands, ear notches and tags, microchips, tattoos and freeze bands. Toe clipping is only acceptable when other methods of identification cannot be used and must be performed under appropriate anesthesia.

Records of rodents, birds, and ectotherms may consist of cage or rack cards, and must indicate, at minimum, the source of the animal, strain or stock (if pertinent), numbers, age, protocol number, and sex of the animals and names of the responsible investigator. Written records of procedures, drug use, illnesses and injuries, and pertinent dates such as surgical procedures or injections should be noted on the cage card or in separate record books kept in or near the animal room. It is the responsibility of the investigator to maintain individual clinical records for all animals.

Animal records should be maintained for 3 years after completion of a project and are subject to inspection by the USDA, NIH site visitors and other accredited bodies.

c. **Euthanasia/Disposition of Animals:** Euthanasia is the act of inducing painless death. The selected method of euthanasia must be consistent with the recommendations of the June 2007 AVMA Guidelines on Euthanasia. The selection of the method of euthanasia should be according to the following criteria: 1) its ability to induce loss of consciousness and death without causing pain, distress, anxiety, or apprehension; 2) the time required to induce loss of consciousness; 3) its reliability; 4) safety to personnel; 5) irreversibility; 6) its compatibility with the requirements and purpose of the research; 7) its emotional effect upon observers or operators; 8) compatibility with subsequent evaluation, examination, or use of tissue; 9) drug availability and human abuse potential; 10) compatibility with species, age, and health status; 11) ability to maintain equipment in proper working order; and 12) safety for predators/scavengers should the carcass be consumed.

The most desirable euthanizing techniques are those that produce a rapidly occurring unconsciousness followed by cardiac or respiratory arrest. Selection of the most appropriate method of euthanasia is dependent upon the species and weight of the animal involved,

available means of animal control, skill of personnel, numbers of animals, objectives of the protocol and other considerations.

Physical methods such as decapitation and cervical dislocation are the least desirable euthanasia methods, but can be humane techniques when carefully performed. The use of either is permissible but discouraged. Because of their high flammability and toxicity either and other halogenated gaseous anesthetics as methods of euthanasia are permissible only if adequate scavenging is available. Use of an injectable agent such as an overdose of pentobarbital is considered the most desirable method. Carbon dioxide is the recommended inhalant agent.

4. Required Training

- a. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

DePaul University has adopted the Collaborative Institutional Training Initiative (CITI) online training program to provide the required education to animal care and use personnel. In addition, DePaul has subscribed to the American Association for Laboratory Animal Science (AALAS) Learning Library, which allows all personnel access to these educational resources. Individuals will be required to complete the number of modules assigned to their learner group (role) in the animal care program in the CITI online program. The learner groups the DePaul IACUC has created for IACUC/Animal Research training program and that determines the courses and modules people need to take are:

1. Investigators, Staff and Students, Lab Animal Research - This group includes all investigators, co-investigators, and key personnel listed on IACUC protocols, including student researchers and research assistants. This learner group must take the "Working with the IACUC" course.
2. IACUC Chairs, Members and Coordinators, Lab Animal Research-This group includes all IACUC members and Office of Research Services staff that have assigned responsibilities to support the IACUC. This learner group must take two courses, "Working with the IACUC" and "Essentials for IACUC Members."

Required Training for Investigators and Key Personnel

All investigators and key personnel are required to complete the following types of training:

- Basic-Initial training: Working with the IACUC -- Investigators, Staff and Students, Lab Animal Research (required)
- Species Specific Training (required for personnel listed on the protocol)
- Protocol Specific Training i.e. surgical training, pain monitoring training (if applicable to the protocol and their role in the protocol)

BASIC INITIAL TRAINING - WORKING WITH THE IACUC

Basic Initial training is required for investigators (including co-investigators), staff (including research assistants) and students (undergraduate and graduate) who are listed on an IACUC application as key personnel involved in the conduct of the activity outlined in the protocol. When registering in the CITI program Investigators and key personnel (including co-investigators, student researchers and research assistants) should choose the "Working with the IACUC" course under Animal Care and Use Courses.

For Investigators who are conducting field or observational studies, they must complete the Wildlife Training Modules from the American Association for Laboratory Animal Science (AALAS) Learning Library instead of CITI's Working with the IACUC training.

SPECIES-SPECIFIC TRAINING

Principal Investigators (PI) for protocols (including field study and teaching protocols) should provide a description of their experience and expertise with the particular species being utilized in the activity in the initial protocol application. The IACUC will make a determination on a protocol per protocol basis whether the training and expertise of the PI is sufficient or whether additional training will be required.

Species-specific training for protocol personnel may be completed by one of two methods; 1) completing appropriate training modules in the CITI program listed as optional or 2) Completing comparable training through other IACUC approved sources, such as one-on-one training with the protocol Principal Investigator (PI) or training available through the American Association for Laboratory Animal Science (AALAS) Learning Library. Documentation of completion of species-specific training must be on file with Research Protections (RP) in the Office of Research Services before final protocol approval for new protocols, before approval of an amendment adding additional staff can be provided.

Available species specific training modules in CITI include:

- Working with Amphibians in a Research Setting
- Working with Mice in Research Settings
- Working with Rats in Research Settings
- Working with Hamsters in Research Settings
- Working with Gerbils in Research Settings
- Working with Guinea Pigs in Research Settings
- Working with Rabbits in Research Settings
- Working with Zebrafish: *Danio rerio*

When training is not available in the CITI program for a specific species or for a specific procedure, other training resources, such as the American Association for Laboratory Animal Science (AALAS) Learning Library or investigator resources may be utilized.

PROTOCOL SPECIFIC TRAINING (Required when applicable to the protocol or the individual's role in the conduct of the protocol)

If a protocol involves procedures that require additional training, such as survival surgery, monitoring post surgery pain, animal restraint, collecting blood or a protocol involves the use of animals that require special consideration according to the Guide, PHS policy, or Animal Welfare Regulations, additional protocol-specific training modules listed as optional on the CITI course list will be REQUIRED BEFORE final IACUC approval can be provided for the protocol or before a particular person may be involved in the conduct of a specific protocol or procedure.

Protocol-specific training modules available through CITI include the following:

- Surgery
- Antibody Production
- Collecting Blood Samples
- Using Hazardous and Toxic Agents in Animals
- Prolonged Restraint
- Housing Rodents on Wire Floors
- Using Human Patient Care Areas for Animal Research
- Primate Psychological Enrichment
- Housing Social Animals
- Introduction to Post Procedure Care of Mice and Rats in Research:
- Minimizing Pain and Distress

Additional training may be required related to pain assessment and management for a particular species or surgical procedure, which should be provided by the Principal Investigator to research staff. The training should be specific to the type of procedure being conducted and the type of pain or discomfort expected from the procedure. The training should include how to recognize and assess pain and discomfort in that particular species. Additional training options that are available outside of CITI will be accepted as meeting this requirement, if an investigator justifies why the alternative training option is an improvement over CITI offered modules or if CITI does not offer appropriate training. The IACUC must pre-approve any alternate training options.

CONTINUING EDUCATION

DePaul requires that all individuals involved in the animal care and use program complete continuing education. Personnel must complete a minimum of 1 contact hour of continuing training/education every 3 years after initial training. For example, if you complete initial training on 12/1/12 you will be required to take continuing education prior to 12/1/15. The goal of continuing education is to keep research personnel current in their knowledge and to ensure personnel are informed of changes to PHS policy, the Animal Welfare Regulations, and DePaul policy and procedures.

Principal Investigators, co-investigators, and key research personnel may fulfill the continuing education requirement by participating in one of the following:

- Attending animal research training seminars presented at another institution or through national or regional training conferences focused on animal research. The seminar, conference, or training must be pre-approved by the Office of Research Services (ORS) and ORS must receive documentation of attendance from the individual.
- Completing the CITI online Lab Animal Welfare Refresher training.
- Completing training from the AALAS library. The Office of Research Services must receive documentation of training from the individual.

Required Training for IACUC Members and Research Services Staff

All IACUC members and Research Services staff assigned to duties supporting the IACUC must complete basic initial IACUC/Animal research training and continuing education every three years.

BASIC INITIAL TRAINING

IACUC members and Research Services staff should choose the "Essentials for IACUC Members" course, the "Working with the IACUC" course, and Post-Approval Monitoring (PAM) course under Animal Care and Use Courses. If personnel have more than one role in the Animal Care and Use Program, such as investigator and IACUC member, then they will need to complete the training at the highest level of responsibility and highest number of modules/courses. In the case of investigators who are also IACUC Members, that means choosing three courses, the "Essentials for IACUC Members," "Working with the IACUC," and "Post-Approval Monitoring." After choosing the correct learner group, the following courses should be selected and added to the individual's course list.

- Working with the IACUC -- Investigators, Staff and Students, Lab Animal Research; (required)
- Essentials for the IACUC - IACUC Chairs, Members and Coordinators, Lab Animal Research (required)
- Post-Approval Monitoring (PAM) (required)

In addition to the formal training all new IACUC members are required to complete an orientation session in which local policy and procedures are reviewed. All IACUC members are provided with a resource binder that includes copies of DePaul's assurance, federal laws and guidelines, DePaul policy, IACUC forms, and other pertinent resources and educational materials.

CONTINUING EDUCATION for IACUC Members and Research Services Staff

DePaul requires that all individuals involved in the animal care and use program complete continuing education. Personnel must complete a minimum of 1 contact hour of continuing training/education every 3 years after initial training. The goal of continuing education is to keep research personnel current in their knowledge and to ensure personnel are informed of changes to PHS policy, the Animal Welfare Regulations, and DePaul policy and procedures.

IACUC members will complete continuing education by attending meetings and participating in the educational sessions provided at each meeting. Additionally, IACUC members may complete additional continuing education by any of the following methods:

- Attending animal research training seminars presented at another institution or through national or regional training conferences focused on animal research. The seminar, conference, or training must be approved by the Office of Research Services and ORS must receive documentation of attendance from the individual.
- Completing the CITI online Lab Animal Welfare Refresher training.
- Completing training from the AALAS library. The Office of Research Services must receive documentation of training from the individual.

Required Training for Animal Care Staff

INITIAL TRAINING

Animal care staff must complete training, but training may be on the job training or from the American Association of Laboratory Animal Science (AALAS) library. Animal care staff are supervised and trained by the Research Support Facility (RSF) Director. Documentation of training for animal care staff should be maintained by the RSF Director. Documentation should include the type of training completed (including the source of training, i.e. AALAS, investigator, RSF Director), the person who received training, and the date of the training. Topics for animal care staff training should include, but are not limited to:

- DePaul policy and RSF policy
- Animal husbandry
- Diet
- Animal handling and restraint
- Animal behavior and health observations
- Sexing and breeding
- Caging/tank systems and equipment mechanics
- Cage/tank sanitation
- Facility sanitation
- Environmental monitoring
- Vermin control
- Personal safety and hygiene
- Security
- Disaster plan response procedures

Additional species-specific training should be provided to Animal Care staff by individual investigators with animals housed in the RSF. For example, species-specific training regarding how to provide daily care or how to feed and water the animal should be provided by individual PIs to animal care staff using written SOPs that become attachments to the Research Support Facility (RSF) Policy and Procedure Manual. Any training provided to animal care personnel should be documented and the documentation should be provided to the RSF Director. Copies of the training documentation should be kept in the animal facility.

CONTINUING EDUCATION for Animal Care Staff

Animal Care Staff may complete continuing education by any of the methods listed above for investigators as long as the training is pertinent to their role and duties as animal care technicians. For example, the AALAS library has training programs specifically for animal care technicians. Animal Care Staff may also meet the continuing education requirement by receiving ongoing on-the-job training from investigators and the RSF Director or the RSF Assistant Director. The RSF Director should ensure that any training received is documented and documentation of training is kept in the RSF where it can be reviewed by the IACUC.

Animal care staff members are encouraged to complete certification programs to demonstrate their expertise and proficiency.

Collaborating Investigators, Subcontractors at Other Institutions, AND NON-DEPAUL PERSONNEL

Many research projects involve collaborators or personnel who are not DePaul students, faculty or staff. These collaborators or non-DePaul personnel may be at other academic institutions. When activities will be conducted at another institution that has their own IACUC, collaborators do not need to meet DePaul training requirements provided that the collaborators have fulfilled local educational requirements mandated by the IACUC at their own institution. Collaborators may provide documentation of training from their local institution or a copy of the local IACUC approval, which would signify they have met the training requirements locally. If the collaborator or other non-DePaul personnel will be conducting any animal related activities at DePaul, they would need to meet the DePaul training requirements. If they have completed similar training at their local institution, the DePaul IACUC may accept documentation of training from the collaborators local institution, if it is comparable to DePaul's training. The IACUC will make this determination on a protocol per protocol basis.

When an activity involves collaborators or other personnel who do not have an IACUC or a local equivalent, such as might be possible when conducting activities in foreign countries or when conducting field studies using local people as assistants, the PI of the DePaul protocol must include in their protocol a plan for providing training to these personnel who will be actively involved in the conduct of the activity and who will have direct contact with the animals utilized in the activity. The training plan should include general animal care and use topics, species specific topics, and protocol-specific topics that would pertain to the person's role in the activity with the ultimate goal of protecting the health and well-being of the animals and the health and safety of the person.

Verifying Required Training

The Principal Investigator (PI) is responsible for listing all key personnel that will be involved in the conduct of the activity described in the IACUC protocol including any collaborating or non-DePaul personnel. When the PI signs the assurance page of the IACUC application s/he is certifying that each person listed who must complete the DePaul training requirements has already completed the required training and that her/his research records contain copies of the training documentation. The Principal Investigator (PI) is ultimately responsible for ensuring all

research personnel listed on their protocol has completed required basic training and any special protocol-specific or species-specific training. The PI should document what training is provided, the person who received training, and the date of training in their study records and provide this information to the ORS, when necessary. When personnel are added to a protocol via an amendment, the PI is responsible for ensuring the appropriate training has been completed and documented.

- b. Occupational Health and Safety Program for the Animal care and use Program: DePaul maintains a risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals.

DePaul's IACUC and the Office of Research Services works closely with the DePaul Environmental Health and Safety (EHS) Office. EHS maintains general policies related to occupational health and safety, OSHA regulations, personal hygiene, handling chemical agents, and personnel protection. EHS makes sure that DePaul policies and procedures are aligned with federal and local laws and regulations pertaining to chemicals usage, spills, and OSHA employer responsibilities. Additionally, EHS conducts an annual risk assessment in the Research Support Facility (RSF- DePaul's animal facility) and in individual faculty laboratories when Biosafety Level 2 agents are utilized in that lab. For details regarding any policies and procedures for EHS go to: <https://offices.depaul.edu/environmental-health-and-safety/manuals-procedures/Pages/default.aspx>

As part of EHS policy all students and faculty involved in lab courses must take annual lab safety classes. Additionally, all persons working with materials that could contain blood borne pathogens must take annual blood borne pathogen training. Finally, EHS offers annual OSHA training which covers topics such as ladder safety, back safety, electrical safety and personal protective equipment (PPE).

In addition to general EHS policies, DePaul has developed an Animal Care and Use Program Occupational Health and Safety Policy and Procedure Manual, which outlines policies specific to persons working with or who have exposure to animals as part of the animal care and use program. Personnel covered by these policies include faculty, staff and students who conduct research, research training, teaching, experimentation, biological testing, exhibition, and related activities under the purview of DePaul's Animal Care and Use Program and that involve direct contact with live vertebrate animals (either at DePaul or in the field), direct contact with non-sanitized animal caging or enclosures, direct contact with non-fixed or non-sterilized animal tissues, fluids, or waste, or who provide support to the animal facilities (i.e., facility animal care staff), or provide compliance review services, and any visitors who are exposed to live animals, animal tissues, or waste while at DePaul.

Control and Prevention Strategies

Control and prevention strategies begin with the identification of hazards and the assessment of risk associated with those hazards. DePaul's EHS, Institutional Biosafety Committee (IBC), the IACUC, and the Office of Research Services (ORS) work together to identify any risks, assess the level of risk, and to mitigate those risks. Ongoing

assessment is needed to ensure that the risks associated with working with the animals and in the animal facility, in general, are clearly identified and so that appropriate strategies to minimize or manage the risks are developed as new risks emerge over time.

Hazard Identification and Risk Assessment

Potential risks related to the work environment are identified during the annual risk assessment conducted in the RSF by EHS. The ORS accompanies the EHS and/or receives a written report of the risk assessment. ORS works with EHS and facility management to correct any issues identified. Risks associated with infectious agents or toxins or any biohazardous agents, as defined by the Institutional Biosafety Committee (IBC) policies are identified and mitigated during the review of protocols submitted to the IBC. Risks related to chemicals are mitigated by the chemical hygiene plan maintained by EHS. General risks, such as wet floors, ladders, and noise are part of the EHS OSHA training and risk assessment.

The design of the animal facility, the use of safety equipment, the development of standard operating procedures (SOPs), and the provision of appropriate personal protective equipment for persons in the facility and laboratories working with animals occurs as part of the annual risk assessment conducted by EHS, and as part of the protocol review process by the IACUC (for animal specific risks). For field studies with animals a special form is used to identify the risks and the possible ways to mitigate the risks. These forms are reviewed administratively by ORS IACUC staff, who may request additional expertise outside of DePaul, when needed. Policies and procedures are reviewed annually as part of the programmatic review and are revised as needed. SOPs are developed based upon an identified need to do so and as the program expands additional SOPs are developed.

Facilities, Equipment and Monitoring

The facilities are assessed and monitored on an ongoing basis by the Director of the Research Support Facility. The Director maintains the cleanliness of the facility and ensures personnel are properly trained to use equipment and are provided with the appropriate personal protective equipment (PPE). The Director assesses animals and animal rooms daily to ensure environmental controls are working properly and that the heating, ventilation, and air conditioning (HVAC) system is working properly. Safety features such as eye wash stations and emergency showers are in the facility or are assessable from the facility. To the best of our ability, remodeling of the facility and the selection of supplies are made to minimize risks to individuals and are appropriate to the type and level of risks identified. Animal housing improvements in caging have been ongoing to upgrade our caging systems to minimize exposure to contaminated food, bedding, feces, and urine. SOPs outline proper procedures for cleaning cages and disposal of soiled bedding.

Personnel Training

As noted above EHS requires annual training be completed by faculty, and students related to general OSHA occupational safety practices. In addition, persons working with animals must complete the CITI IACUC training modules, which includes information about animal-specific risks. The PI of a particular protocol must also provide protocol-

specific, and species-specific training to their staff pertaining to any special equipment or procedures that may be part of that protocol. In addition, before anyone can work in the RSF (animal facility), they must complete an orientation session with the Director of the RSF which includes a tour of the facility, instructions for using certain equipment, SOPs related to the facility, and proper PPE while working in the facility.

Personal Hygiene

All persons working with animals in the animal care program must demonstrate the use of good personal hygiene to prevent occupational injury and cross contamination. Appropriate PPE is provide in the animal facility and in laboratories and the use of proper PPE is strictly enforced. Soiled attire is either disposed of (i.e., disposal gowns, disposable, gloves, disposable respirators or face masks) or laundered weekly (lab coats, and RSF staff scrubs). Personnel are instructed to wash and sanitize their hands frequently. Garments worn in the facility are not worn outside the facility and personal items are stored in lockers. Personnel are not allowed to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in animal rooms or laboratories where animals are housed or used. This information is clearly stated in the occupational health and safety policies and in signage in the facility.

Animal Experimentation Involving Hazards

When animal experimentation with hazardous agents is conducted special attention is paid to animal care and housing, storage and distribution of the agent, dose preparation and administration, body fluid and tissue handling, waste and carcass disposal, items that might be used in the facility and then removed (i.e., equipment, sample vials, written records), and personal protection. The IACUC and the IBC work together to ensure that all these areas of concern are addressed. The IBC and EHS policies address experimentation with biohazardous agents, chemical agents, and physical agents. The IBC ensures that appropriate procedures are in place when working with biohazardous agents in compliance with the the National Institutes of Health (NIH) Guidelines for Recombinant and Synthetic Nucleic Acid Molecules and Biosafety in Microbiological and Biomedical Laboratories (BMBL). When necessary the air flow in the areas where the hazardous agent will be utilized is adjusted to control exposure to the agent.

Personal Protection

Clean PPE is provide, as needed, and is appropriate to the work being conducted by the individual. Anyone working with hazardous materials are provided with appropriate PPE based upon the hazard, such as the appropriate respirator mask. Depending upon the species of animal being utilized, the PPE is adjusted to ensure the safety of the individual. Hearing protection is provided in high noise areas, like the cagewash. Personnel are supplied with appropriate respirators or face protection, based upon the area they are working in or the duties they perform. Fit testing is provided for respirators in compliance with OSHA regulations.

Medical Evaluation and Preventative Medicine for Personnel

DePaul has developed the policy and procedure manual called Occupational Health and Safety Program for the Animal Care and Use Program. The policy was developed in order to be

compliant with the standards of the Guide. Under the policy, all faculty, staff and students who conduct research, research training, teaching, experimentation, biological testing, exhibition, and related activities under the purview of DePaul's Animal Care and Use Program and that involve direct contact with live vertebrate animals (either at DePaul or in the field), direct contact with non-sanitized animal caging or enclosures, direct contact with non-fixed or non-sterilized animal tissues, fluids, or waste, or who provide support to the animal facilities (i.e., facility animal care staff), or provide compliance review services, and any visitors who are exposed to live animals, animal tissues, or waste while at DePaul must have an initial medical assessment conducted, followed by an annual medical assessment as long as they continue to work with animals at DePaul. The assessments are to be conducted by Presence Health. The procedures are as follows:

- All persons who need to enroll in the occupational health and safety program will complete a short form that allows ORS staff to assess whether they must complete a health screening and/or be fitted for a respirator. This form does not contain medical information, but rather requests a summary of their role in the animal activity and what procedures they may conduct. Based upon the review of this form administratively, the individual will be instructed to complete the health questionnaire and respirator fit testing, when applicable.
- Persons who are required to do so will complete the health screening questionnaire and send it to Presence Health.
- The medical personnel at Presence Health will review the information and if they have questions, they will contact the individual. If everything looks fine, the person will be cleared and ORS IACUC support staff will be notified the individual has been cleared. If additional medical follow-up is needed, Presence Health will contact the individual and have them come to the clinic to conduct any testing or physical evaluations that are needed. When applicable, the person will also be fit tested for a respiration/face mask.
- At least annually, each person still involved in the animal care and use program must complete an updated assessment. At times, more frequent periodic follow-up risk assessments may be necessary, based upon the needs of the individual and their pre-existing conditions, to ensure there are no new health risks or work-related risks that need to be reviewed with individuals (such as for persons who become pregnant).

Immunizations

Before work with animals begins, immunizations should be reviewed as part of the initial health screening assessment process to ensure that personnel have a current tetanus shot, hepatitis B vaccinations (when working with human blood, tissues, cell lines, or stocks or animals infected with the hepatitis B virus), or other vaccinations, if needed for specific agents utilized in the work. When related to the animal care and use program, immunizations will be provided by Presence Health as coordinated by ORS staff working with the IACUC.

Individuals who work closely with live animals are at increased risk for animal bites and other puncture wounds. A current tetanus shot is highly recommended for everyone who works closely with, or has direct exposure to animals. If the person has not had tetanus shot within the last 10 years or cannot recall the date of the last tetanus shot, arrangements should be made to receive the tetanus shot as soon as possible. DePaul personnel may receive a tetanus shot from Presence Health by indicating they need one on the initial or annual health screening

questionnaire or by calling the Director of Research Compliance in ORS. The Director of Research Compliance will coordinate the receipt of the vaccination from Presence Health when it does not occur during the initial or annual assessment time points. For employees of DePaul, if an injury occurs and a tetanus shot is recommended as part of treatment, the cost of the immunization may be covered by DePaul University's Workmen's Compensation program. For this process, the person must contact DePaul's Office of Risk Management and provide the necessary information for the workmen's compensation claim.

Allergy Screening

Personnel should be screened for allergies during the initial screening process. A medical surveillance program, which includes an evaluation of an individual's medical history for pre-existing allergies, would also include ongoing monitoring for the development of new allergies. Personnel should be trained about animal allergies, preventive control measures, early recognition and reporting of allergy symptoms, and proper techniques for working with animals. If PPE for respiratory protection is necessary, appropriate fit testing and training on proper use of the PPE should be provided. For the animal care and use program, face mask fitting services, when needed, are provided by Presence Health and is coordinated by the Director of Research Compliance in ORS.

All allergic reactions occurring as a result of working with animals housed in the RSF must be reported to the RSF Director, who will complete an incident report form and contact Public Safety with a report. The person should then seek medical attention from their personal physician. All adaptive steps must be taken to minimize contact with allergens. Appropriate engineering controls and PPE including a laboratory coat, gloves and masks should be utilized. Appropriate animal restraint, such as the use of forceps, can reduce allergen transmission as well.

Zoonosis Surveillance

All personnel should be made aware of the potential risk for contracting a zoonotic disease from animals. Zoonosis can be acquired through various routes of infection, including contact with animal products, the animal itself, or a byproduct of the animal. The routes of infection include ingestion, inhalation, and penetration of broken or unbroken skin, wound penetration, and contact with the mucous membranes of the eye, nose, and mouth via animal bites and scratches, contact with animal tissues, cultures, body fluids, and excreta, inanimate objects that are contaminated by the animal or through animal contact, and exposure to aerosols produced as a result of activities such as cleaning ages. Proper adaptive measures must be taken (i.e., wearing gloves and face masks/face shields, proper animal restraint, etc.) to minimize the risk of zoonotic transmission. While animals bred specifically for animal research pose little risk for carrying zoonotic diseases, proper measures must still be taken. Wild animals being handled in the field pose a much greater risk for transmitting a zoonotic disease to researchers including rabies virus, hanta virus, bubonic plague and Lyme disease. Consultation with the Institutional Veterinarian, Presence Health, and/or Environmental Health and Safety for zoonotic concerns and adaptive measures to be taken to minimize likelihood of transmission may be needed.

Personnel shall take all adaptive steps to minimize the likelihood of zoonotic transmission. In addition to being aware of the potential diseases, all appropriate PPE are worn and animals restrained in a safe manner to reduce bite/scratch risk. All personnel should receive training

regarding potential zoonotic diseases related to the type of animal they are working with from the PI, the Director of the RSF, or the veterinarian. All training should be documented and the documentation of training maintained in the RSF in either the RSF records (for animal care technicians) or in the PI records (for personnel working on specific protocols). Personnel should be under constant surveillance for any zoonotic illnesses and should be aware of reporting procedures should they exhibit known symptoms of zoonotic illnesses.

All accidents, bites, scratches and allergic reactions should be reported immediately to the RSF Director, who will inform the Principal Investigator (PI) of the specific protocol to which the animals are assigned. Additional reporting requirements may apply, depending upon the nature of the injury and whether or not the individual was exposed to an infectious agent or whether the individual is an employee or not.

Bite and scratch wounds inflicted by laboratory animals may cause serious injury. Even bites which appear minor may cause significant problems later due to resultant bacterial infection. Bites from wild caught animals may also cause significant infection, depending on their oral flora. Scratch wounds may similarly become infected or may cause mild to moderate allergic reactions. Larger species and wild mammals may cause serious injuries. Vascular lacerations from such bites may pose immediate threat to life.

There is a bite/scratch kit located in room 155 of the RSF, near the first aid kit. A Povidone-Iodine scrub brush is provided. The wound should be scrubbed with this brush for a minimum of 15 minutes. Use a timer if necessary. If the wound is not serious, after the scrubbing, first aid should be applied (antibiotic ointment and a bandage). The RSF Director will then fill out an internal incident report.

All injuries, including bite and scratch wounds and related illnesses must be reported to the RSF Director (directly or using her emergency contact information), who will complete a short internal incident report and report the incident to Public Safety. Public Safety will triage the incident and contact the appropriate person within DePaul responsible for OSHA recording and reporting. This person may then contact the injured party for additional information and the completion of the OSHA form 301 Injury and Illness Incident Report form, if deemed necessary according to OSHA guidelines. Some information is provided below regarding the OSHA recording and reporting requirements, but the final decision about the documentation requirements for an incident lies with the individual responsible for OSHA recording and reporting at DePaul. Therefore, all incidents should be reported to Public Safety so that an evaluation of the need to record and report can be made. If necessary, the person should then seek medical attention at Presence Health for minor injuries (small bites scratches, etc.) or Illinois Masonic Emergency Room for more severe injuries (lacerations requiring stitches, puncture wounds, etc.). Injured persons may also contact Public Safety (773-325-7777) for transportation, if necessary, and to fill out a report or they may see their personal physician. Zoonotic diseases present additional risks. A description of potential zoonotic diseases should accompany the individual to present to medical providers if the risk of transmission is high. When employees are injured, medical costs and lost wages that result from the injury are covered under Workmen's Compensation. The reporting process (i.e., RSF Director and Public Safety) is the same for non-employees and students with the goal of ensuring proper care and follow-up is provided.

OSHA requires that the employer complete an incident report for each recordable case (using the OSHA form 301), keep a detailed log of work-related injuries to employees in a form 300, and then maintain an annual summary of injuries in Form 300A. The summary is supposed to be posted in a visible location. An injury or illness is work-related when an event or exposure in the work environment caused or contributed to the condition or significantly aggravated a preexisting condition. The following are types of work-related injuries that should be recorded:

- Death,
- Loss of consciousness,
- Days away from work,
- Restricted work activity or job transfer, or
- Medical treatment beyond first aid.

Additionally, an employer must record any work-related injuries or illness that are significant or meet the following criteria:

- Any significant work-related injury or illness that is diagnosed by a physician or other licensed health care professional.
- Any work-related case involving cancer, chronic irreversible disease, a fractured or cracked bone, or a punctured eardrum
- Any needle stick injury or cut from a sharp object that is contaminated with another person's blood or other potentially infectious material,
- Any case requiring an employee to be medically removed under the requirements of the OSHA health standard,
- Tuberculosis infection as evidenced by a positive skin test or diagnosis by a physician or other licensed health care professional after exposure to a known case of active tuberculosis
- An employer's hearing test reveals that 1) that the employee has experienced a Standard Threshold Shift (STS) in hearing in one or both ears and 2) the employee's total hearing level is 25 decibels or more above audiometric zero in the same ear(s) as the STS.

For the purposes of the OSHA regulations, medical treatment means managing and caring for a patient for the purpose of combating disease or disorder. The following are not considered medical treatments and are NOT recordable:

- Visits to a doctor or health care professional solely for observation or counseling;
- Diagnostic procedures, including administering prescription medications that are used solely for diagnostic purposes; and
- Any procedure that can be labeled first aid.

For the purposes of OSHA reporting, incidents that require only first aid treatment do not need to be recorded, including the following:

- Using non-prescription medications at non-prescription strength;
- Administering tetanus immunizations;
- Cleaning, flushing, or soaking wounds on the skin surface;

- Using wound coverings, such as BandAids™, gauze pads, etc., or using SteriStrips™ or butterfly bandages;
- Using hot or cold therapy;
- Using any totally non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc.
- Using temporary immobilization devices while transporting an accident victim (splints, slings, neck collars, or back boards);
- Drilling a fingernail or toenail to relieve pressure, or draining fluids from blisters;
- Using eye patches;
- Using simple irrigation or a cotton swab to remove foreign bodies not embedded in or adhered to the eye;
- Using irrigation, tweezers, cotton swab or other simple means to remove splinters or foreign material from areas other than the eye;
- Using finger guards;
- Using massages;
- Drinking fluids to relieve heat stress.

Bite and scratch wounds can often be avoided with appropriate use of PPE and animal handling techniques. Engineering controls and PPE, such as protective gloves and long sleeve lab coats, should always be utilized for work with animals. Proper handling and restraint is also a powerful tool for reducing potential injuries from animals. Do not handle animals until proper training is received from RSF staff or experienced laboratory personnel.

5. Other Procedures and Guidelines for Laboratory Safety

- a. Procedures for Laboratory Emergencies: Laboratory emergencies should be handled in accordance with the procedures established by DePaul, including the Emergency Plan, the Chemical Hygiene Plan, and the Radiation Safety Plan.
- b. Toxic & Hazardous Chemicals: The Office of Environmental Health and Safety works to provide safe study and work conditions within DePaul by addressing the local, state, and federal regulations regarding chemical and occupational issues and affirming compliance.

The Office of Environmental Health and Safety furnishes guidelines and training in safe use of ionizing radiation, hazardous chemicals, blood borne pathogens, and other biological agents. All research personnel, students, and staff working with toxic or hazardous chemicals must complete the Occupational Health & Safety Training and must be retrained on a regular basis. The use of toxic or hazardous chemicals in animal research must be approved by both the IACUC and the Office of Environmental Health and Safety. For additional information about occupational safety requirements or about the appropriate use and disposal of toxic or hazardous agents, contact the Occupational Safety Officer.

DePaul also has policies in place to safeguard the DePaul University community against radiation hazards, and safety guidelines have been compiled to ensure that all appropriate students and staff are aware of the regulations governing radioactive materials use, safety procedures, and disposal requirements. All research personnel, students, and staff working with radioactive materials must complete the appropriate licensing and training requirements, and the use of radioactive materials must be approved by both the IACUC

and the Radiation Safety Officer. For additional information about radiation safety requirements or about the appropriate use and disposal of radioactive materials, contact the Radiation Safety Officer.

c. Personal Hygiene & Personnel Protection

i. Animal Personnel Protection

- Hands should be washed before and after contact with animals even if gloves are used. If hands or other body areas come into contact with tissues, blood, or other body fluids, they should immediately be washed with soap and water.
- Gloves should be worn when having contact with animals to avoid direct contact with tissues, blood, or other body fluids.
- Gowns or plastic aprons are recommended if blood, body fluid, or tissue contact with animals is anticipated.
- If warranted, masks and proper eye protection should be worn when having contact with animals.

ii. Care of Equipment

- Needles & syringes should be disposable and disposed of in a rigid, properly labeled, puncture resistant container and should not be recapped, purposely bent, broken or cut.
- Broken glassware must not be handled by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps.
- Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with materials is finished.
- No mouth pipetting is allowed in laboratories.
- No food or beverages are allowed in laboratories.

iii. Prevention and Control of Exposure to Human Bodily Fluids: Prevention and control of exposure to human bodily fluids should be handled in accordance with the procedures established by DePaul for blood and body fluid precautions

B. IACUC Responsibilities

1. Standards for Approval: In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy. In making this determination, the IACUC will confirm that the research project will be conducted in accordance with the AWA insofar as it applies to the research project, and that the research project is consistent with the NIH Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the research project conforms with DePaul's Assurance and meets the following requirements:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design;

- Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator;
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure;
- The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;
- Medical care for animals will be available and provided as necessary by a qualified veterinarian;
- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;
- Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

2. Conflicts of Interest: An IACUC member who has a conflicting or vested interest in a protocol undergoing IACUC review may not participate in its review or approval, except to provide information requested by the IACUC.

3. Review of Protocols:

a. New Protocols: Due to the small number of animal research projects at DePaul, all new protocols are reviewed under full committee review (FCR) procedures at a convened meeting of the IACUC. When the IACUC receives a new protocol, the protocol is checked for completeness and assigned a protocol number. Protocols are then forwarded to the institutional veterinarian for a pre-review and his/her comments are forwarded to the Director of Research Compliance, which are then communicated in writing to the researcher. If appropriate, the researcher submits a revised protocol application to the Office of Research Services and/or the veterinarian. Once the veterinarian's concerns have been addressed, the protocol will be scheduled for review by the IACUC. All protocol applications are then forwarded to all the IACUC members, and one member of the IACUC, designated by the chairperson and qualified to conduct the review, will serve as primary reviewer on each research project and will be asked to recommend approval or a request for modifications (to secure approval) to the research project.

The IACUC will review each protocol application in a timely fashion. The timeframe for review depends on when the application is submitted, the time it takes the institutional veterinarian to review the original submission, and how quickly the researcher responds to the veterinarian's recommendations. A determination of Approval of for a research project or a request for

modification or additional information may be granted only after review at a convened meeting of a quorum of the IACUC and with the majority vote of the quorum present.

At a convened meeting of the IACUC, the primary reviewer will present the project to the IACUC members, each of which will have reviewed the protocol application prior to the meeting. The IACUC will discuss the project in detail and will make one of the following determinations: approval; Modifications and/or additional information required to secure approval; Tabled; or Disapproval (withhold approval). All review materials and determinations are maintained by the Office of Research Services.

The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

All investigators are informed of the status of their protocol application as well as the concerns and revisions requested by the Committee in a formal letter compiled by staff in the Office of Research Services and the Chair of the IACUC. This letter will be sent to the researcher no later than 5 days after the date of the review. The researcher may email or phone the Chair of the IACUC or the Office of Research Services for an informal notification of outcome. The researcher will have 30 days from the date of receipt to respond to the concerns cited in the memo. The project should not begin before all revisions have been received and the protocol has received final approval from the IACUC.

If the researcher does not respond within the 30-day time period, the following steps will be taken in order below:

- The Office of Research Services issues a written email reminder to the researcher;
- The Office of Research Services will call the researcher to remind him/her that revisions need to be submitted before the deadline date of 90 days after the revisions were formally requested by the IACUC. The IACUC Chair will contact the researcher and explain that the revisions or responses must be submitted before the deadline date of 90-days after revisions were formally requested by the IACUC.
- The IACUC sends a formal memo via email reiterating that the project cannot be approved if appropriate revisions or responses are not submitted by the deadline date of 90 days after the revisions were formally requested by the IACUC.
- If the researcher has not taken action within 90 days, the protocol will be administratively withdrawn from further consideration. If the researcher wishes to obtain approval for that submission, he/she will be required to reinitiate the review process by submitting the materials afresh for IACUC review.

B. Protocol Renewal Process:

Each approved IACUC protocol must be submitted, reviewed, and approved annually (annual renewal) before the expiration date noted in the original approval letter. If a protocol

is conducted for greater than three years, before continuing past the third year, the protocol must be resubmitted as a new protocol and undergo review and approval by the IACUC following the policy and procedures for a new protocol, except that renewals that do not have substantive changes are not pre-reviewed by the veterinarian before sending to the IACUC members. Renewals may be reviewed by Designated Review Member (DMR) or the Full Committee Review (FCR) process.

Designated Member Review (DMR):

Submissions that qualify for a designated member review (DMR) (i.e. Amendments, Renewals, and revisions requested by the convened IACUC) are reviewed by a subcommittee of the IACUC, as assigned by the Chair. The subcommittee will be composed of two IACUC committee members (as assigned by the Chair). If the submission involves animal care concerns, the Veterinarian will be one of the subcommittee members. The subcommittee is assisted by the Office of Research Services staff. When the IACUC requests minor changes to a protocol, the subsequent revised submission may be reviewed by a subcommittee consisting solely of the IACUC Chair and a member of the Office of Research Services staff.

The subcommittee has the authority to approve (if appropriate, by unanimous agreement of the 2 voting members), request modifications and/or information in order to secure approval, or request full committee review (FCR). A protocol cannot be disapproved through the DMR review process. If the DMR decision is split, then the protocol submission must be reviewed by the full committee review process. Designated member review approval has equal validity to full committee review approval and does not require subsequent re-approval by a convened meeting.

All IACUC members are sent submissions eligible for DMR, including revised materials subsequent to convened review (when applicable), and are given 5 business days to comment or request full committee review. If full committee review is requested by any member, the protocol is placed on the next IACUC meeting agenda. If no member calls for a full committee review, then the Chair will assign the review to a selected DMR subcommittee with the expertise to review the protocol.

In instances when the DMR process occurs after a Full Committee Review where the IACUC requested revisions or additional information, the IACUC will follow these procedures:

- If all members of the IACUC are present at the convened meeting at which the protocol is reviewed, the committee may vote to have the required revisions reviewed and approved through the DMR process. In this instance the revisions may go directly to the DMR process without sending an Email containing the revised materials to all members and the 5-day waiting period.
- If all members of the IACUC are not present at the convened meeting at which the protocol is reviewed, the IACUC membership has agreed that a quorum of the members present at the convened meeting may decide by unanimous vote to allow the revisions to be reviewed and approved through the DMR process. Any member of the IACUC may request at any time that the revised materials be reviewed through FCR. In this instance the revised

materials will be sent out to all IACUC members and the required 5-day time period for members to call for FCR will be observed.

Notification of approvals made through the DMR process will be noted in subsequent meeting agendas and minutes so that all members are informed of the actions taken in the IACUC's name. It is always possible for any member of the IACUC to discuss any protocol submission reviewed by any method at any convened meeting, and to have those comments entered into the minutes, as a form of ongoing monitoring of the protocol or in response to animal welfare concerns.

Annual renewal submissions that meet the following criteria may be reviewed using DMR procedures:

- Annual renewals with no changes,
- An annual renewal with no changes except for an increase of animal numbers less than 10% (rodents [rats, mice] and fish only),
- An annual renewal with no changes except change in species, and
- An annual renewal with changes to animal care and/or use procedures that are expected to involve no more than momentary pain or distress (as determined by the IACUC Chair or designee)

If a renewal does not meet the above criteria for DMR, one or more of the IACUC members indicates the submission should be reviewed by the full committee, or the DMR decision is split, the renewal submission will be reviewed by the full convened IACUC. The review of a renewal via FCR occurs as outlined above for new protocols. Changes to the research made at the time of renewal require that the type of changes be identified on the renewal form, that the investigation provides justification for the changes, and that the investigator provides a discussion of how the changes relate to the overall project goals.

- c. Revisions or changes to the approved protocol: Researchers who wish to make changes to a protocol that have been previously fully approved, other than at the time of renewal, must submit an Amendment Form and applicable revised application materials to the Office of Research Services. Revised protocols are then forwarded to the Chair for determination of type of review: Designated Member Review; or Full Committee Review.

The types of revisions that are considered to be significant changes that require IACUC review include, but are not limited to:

- Changes to the objective of the a study from non survival to survival surgery;
- Changes resulting in greater discomfort or in greater degree of invasiveness;
- Changes in the species or in the approximate number of animals used;
- Change of Principal Investigator;
- Changes in anesthetic agent(s) or the use of or withholding of analgesics;
- Changes in the method of euthanasia;
- Changes in the duration, frequency, or number of procedures performed on an animal; and
- Changes in or addition of procedures or manipulations

Protocol revisions or amendments to previously approved IACUC protocols may be reviewed under either Designated Member review or Full Committee Review.

The IACUC procedures for reviewing proposed significant and non-significant changes in ongoing research projects are as follows:

Researchers wishing to make changes to a protocol that has been previously fully approved must submit an Amendment Form and applicable revised application materials to the Office of Research Services. When changes are submitted at the same time as the annual renewal, an amendment form detailing the changes must still be submitted. Revised protocols are then forwarded to the IACUC Chair for determination of the appropriate level of review: Designated Member Review; or Full Committee Review. All changes to an approved protocol must receive IACUC review and approval before being implemented.

DePaul University interprets significant (major) changes to mean those that substantially alter or affect the overall study objectives/rationale, specific approved procedures, or the potential for pain, distress and discomfort in the animals or have a direct impact on the health and well-being of the animals. Significant changes require FCR or DMR.

Examples of significant (major) changes that require FCR include, but are not limited to:

- Changes to the objectives of the a study
- Changing from non survival to survival surgery;
- Changes resulting in greater discomfort or in greater degree of invasiveness;
- Changes in the species or in the approximate number of animals used;
- Change of Principal Investigator or key personnel involved in animal procedures;
- Changes in anesthetic agent(s) or the use of or withholding of analgesics;
- Changes in the method of euthanasia;
- Changes in the duration, frequency, or number of procedures performed on an animal; and
- Performing a new procedure or changing the procedures or manipulations being used

Significant changes that impact the health and safety of the animals, but to a lesser extent may be reviewed under DMR. Examples of significant (major) changes that may be reviewed under DMR include, but are not limited to:

- An increase of animal numbers less than 10% (for rodents [mice, rats] and fish only);
- A change in strain within the same species;
- A change in animal care and /or use procedures that are expected to involve no more than momentary pain or distress (as determined by the IACUC Chair);

DePaul University interprets non-significant (minor) changes to mean those that do not have the potential to directly or substantially impact the health and well-being of the animals. Non-significant (minor) changes may be reviewed administratively

Significant changes that may be handled administratively in agreement with IACUC reviewed and approved policies and procedures (approved SOP and checklist/review guide for VVC) and in consultation with the DePaul Institutional Veterinarian through the Veterinary Verification and Consultation (VVC) process include:

- Changes in anesthesia, analgesia, sedation, or experimental substances;
- Changes in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
- Changes in duration, frequency, type, or number of procedures performed on an animal (but not entirely new procedures).

Under VVC, the veterinarian is not conducting DMR, but is instead serving as a subject matter expert to verify that compliance with the IACUC-reviewed and approved policy is appropriate for the animals in this circumstance. When this method of review is utilized, the veterinarian consultation will be documented using an IACUC approved review guide. The veterinarian may make the verification or determine that the change needs to be reviewed by the IACUC for any reason or he/she may determine that the request does not meet the parameters of the IACUC-reviewed and approved policies (SOP) for veterinarian consultation and that the change must be referred for FCR.

DePaul University interprets non-significant (minor) changes to mean those that do not have the potential to directly or substantially impact the health and well-being of the animals. Non-significant (minor) changes may be reviewed administratively.

Changes that may be reviewed administratively by the Office of Research Services staff include:

- A change in personnel, other than the Principal Investigator for an existing approved protocol (with administrative review that personnel have been appropriately identified, adequately trained, are qualified, and meet other criteria of the IACUC);
- A change in funding status or source;
- A change in the animal source or vendor;
- Changes in Research Support Facility room location or addition of a laboratory space;
- Correction of typographical errors;
- Correction of grammar; and
- Contact information updates

Amendments limited to the above changes are reviewed by the Office of Research Services after verifying training for new personnel. If there are any perceived animal welfare concerns, the ORS staff may request that the IACUC Chair refer the protocol amendment to a higher level of review (i.e. designated member review, full committee review).

The use of fewer animals than approved does not require handling through IACUC policy, approval, notification, consultation, or administrative handling.

Meeting minutes, detailing protocol reviews, will be compiled and sent to the Institutional Official (IO) every 6 months along with the semiannual program review and facilities inspection reports. In the case of a disapproval (withhold approval), the IO is notified of the Disapproval determination and the reasons for Disapproval in writing at the same time as the Principal Investigator.

4. Reminders of Project Expiration Dates:

Each year the researcher must submit a protocol renewal form and an update for the project, clearly indicating any proposed changes, whether minor or substantive. Substantive changes in the protocol require submission of a revised protocol application. Renewals are reviewed either by administrative review, designated member review, or by the full committee review, in accordance with the procedures for renewals to an approved protocol as described above, except that renewals do not receive a preliminary review by the veterinarian unless there have been substantive changes.

Renewals must be fully approved prior to the anniversary of the original IACUC review. Approved projects may be renewed annually for up to two additional years, but, after the completion of the third year, a new protocol application must be submitted if the project will continue.

The Office of Research Services issues notices for approved projects at the appropriate time each year, reminding researchers that they must renew protocols that will continue past the anniversary date of the original reviews. If a project has been renewed twice already, the Office of Research Services issues a request for information about whether the project will be resubmitted, canceled, or transferred. Resubmissions are then reviewed in accordance with the procedures for new protocols as described above.

5. Suspension of Activity: The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the AWA, the NIH Guide, DePaul's Assurance, or IV.C.1.6. of the PHS Policy.

The activity in question would be considered by a quorum of the IACUC at a convened meeting. The IACUC would discuss the matter in detail, in order to determine whether the activity complies with the Animal Welfare Act, the Guide, DePaul University's Assurance, and/or PHS policy. The IACUC would vote on the issue, and the activity would be suspended if a majority of the quorum so voted. All suspended activities would be reported in writing to the Institutional Official promptly. The IO would then issue a written report to the USDA, OLAW, and if federally funded, to the funding agency.

Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are the Chair of the IACUC and the Director of Research Compliance.

6. Facility Inspections & Programmatic Reviews: As specified in PHS Policy at IV.A.2, as Category 2 institution, all of DePaul's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1-2 of the PHS Policy, and reports have been and will be prepared in accord with IV.B.3 of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the NIH Guide. Any departures from the NIH Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency.

Semiannual reports of the IACUC evaluations will be submitted to the Provost. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare upon request.

7. Record Keeping: This institution will maintain for at least three years:

- A copy of Assurance and any modifications thereto, as approved by the Public Health Service.
- Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
- Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
- Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official.
- Records of accrediting body determinations.

This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion the activity.

All records shall be accessible for inspection and copying by authorized United States Department of Agriculture, Office of Laboratory Animal Welfare, or other Public Health Service representatives at reasonable times in a reasonable manner.

8. Reporting: At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare:

- Any changes in the accreditation status of the institution (e.g. if the institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any changes in the description of the institution's program for animal care and use as described in the Assurance, or any changes in the IACUC membership. If there are no changes to report this institution will provide OLAW with written notification that there are no changes.

- Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official.

The IACUC, through the Institutional Official, will provide OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with PHS Policy.
- Any serious deviations from the provisions of the NIH Guide.
- Any suspensions of an activity by the IACUC.

Reports filed in this section shall include any minority views filed by members if the IACUC.

Divisional Collaborations

Academic Affairs-Office of Research Services
College of Science and Health
Department of Biological Sciences
Department of Health Sciences
Office of Environmental Health and Safety

Contact Information

Institutional Animal Care & Use Committee

<http://offices.depaul.edu/ors/research-protections/iacuc/Pages/default.aspx>

Director of Research Compliance

sloesspe@depaul.edu

(312) 362-7593 (phone)

Appendices

A. [Basic Biologic & Physiologic Values of Common Laboratory Species](#)

B. [Recommended Anesthetics & Analgesics](#)

C. [Additional Readings](#)

History/Revisions

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