

INSTRUCTIONS FOR COMPLETING
"APPLICATION TO USE VERTEBRATE ANIMALS"

INTRODUCTION

University policy and federal law require a review of projects for humane treatment and judicious use of vertebrate animals. At Eastern Michigan University, adherence to this policy and federal law is assured by the Institutional Animal Care and Use Committee (IACUC) through review of the Application to Use Vertebrate Animals. In fulfilling its responsibility to ensure the judicious use of animals, the IACUC does not generally review applications for scientific or instructional merit, but rather requires evidence of scientific and instructional merit, such as awards from peer-reviewed funding agencies. Applications which are not currently funded may be submitted to and reviewed by the Committee if required by the granting agency.

Projects Requiring Review

Principal investigators and course directors must obtain approval from IACUC before initiating any research, testing, or instructional project involving the use of vertebrate animals. Failure to do so is a violation of federal law.

The following types of animal use do not require IACUC review:

- invertebrate animals;
- whole dead animals not regulated by the USDA [e.g. cold-blooded vertebrates, birds, rats (Rattus only), and mice (Mus only)];
- animal tissues, fluids, internal organs, eggs, embryos, fetuses, etc. obtained as a standard commercial product or as a byproduct of another IACUC-approved research project;
- non-intrusive field research (observation only, no manipulation of the animal or its environment).

If you are uncertain whether IACUC review is required for your project, please contact the Office of the Associate Provost at 487-3277 for a determination.

The Application Review Process

Normally, the application review process takes 4-6 weeks from submission to completion of the review.

Completed applications should be submitted to IACUC, Office of the Associate Provost, 106 Welch. An application number will be assigned. After an administrative review, applications are forwarded to members of the IACUC for a 2 week review period. Principal investigators may be contacted by IACUC by telephone or by E-mail if any issues of concern arise. Once all issues have been resolved to the satisfaction of a majority of the Committee, approval is granted. Following approval, an approval package will be sent to the principal investigator. The approval package will contain the approval letter, a final annotated copy of the approved application, and other pertinent information. The contents of the

approval package must be provided to all personnel involved in the research project because the information in it bears on the animal use activities of each member of the research team. IACUC approved projects that are also funded are termed "activated" and will receive a Protocol Approval Number (PAN, a modification of the Application Number). Activation of approval is required in order to purchase animals and initiate the approved procedures. The Protocol Approval Number must be referenced on animal care and use documents, such as animal requisitions, displayed on individual animal cages and may be requested by outside inspectors.

Approval Period and Annual Review

IACUC approval is valid for a maximum of three years. Each year, principal investigators will be sent and are required to complete, sign, and return a brief Annual Review Form. Completion of this form is required for compliance with the regulations of the Federal Animal Welfare Act. Failure to return the Annual Review Form is a violation of federal law, and will lead to inactivation of IACUC approval to use animals.

Modifying Approved Applications

Prior to making significant changes in animal research activities, investigators must receive approval of the proposed changes from the IACUC. Changes involving animal use will usually require IACUC review. These changes should be described in a "Modification Memorandum" to the Committee. The name of the principal investigator, current Application/Approval Number, and title of the project must be referenced in the "Modification Memorandum". Principal investigators should be sure to describe all aspects in which the change may alter their approved protocol. This is best accomplished by reviewing the currently approved application, and addressing each question affected. For example, a request for additional numbers of animals (Question 6), also necessitates justification of animal numbers in Question 9e. A request for a new species (Question 6), also necessitates justification of animal species (Question 9d), justification of animal numbers (Question 9e), and possibly changes in anesthetics (Question 7), euthanasia methods (Question 8), and animal use procedures (Questions 9). A modification to an approved application undergoes the same review process as do new or renewal applications. Investigators should allow 2-3 weeks for review of modifications by IACUC.

Minor changes to an approved application such as changes in funding, personnel, or facilities also should be submitted to the Committee in a "Modification Memorandum". Minor changes of an administrative nature can usually be processed within 7-10 days.

GENERAL INSTRUCTIONS

This application must be typed or legibly printed.

Questions are presented in standard Courier 12 point font. Answers to questions in the application should be formatted in bold type for the benefit of the reviewers. In addition, you are encouraged but not required to use a font other than Courier for your answers.

Complete the application in its entirety.

Additional space or pages may be added to accommodate the answer to any question. Repaginate word-processed documents or clearly indicate the order of any other added or inserted pages.

Abbreviations must be clearly spelled out and/or defined at first use.

The application has been constructed so that, unless indicated, answers of "Not Applicable" should not be necessary.

Some questions may seem redundant. Such redundancy has been minimized wherever possible. However, due to various reporting requirements, some information must be gathered in particular formats. Applicants may find that they will be asked to provide brief answers regarding issues which they have discussed in detail in another part of the form. Please answer each question as stated, and do not simply refer to another answer elsewhere in the application.

Michigan Freedom of Information Act (FOIA)

Applicants should be aware that approved applications may be obtained through the Michigan FOIA. Applications should be written in a manner which will allow them to sustain public scrutiny. Avoid unnecessary use of inflammatory descriptive language. For example, when discussing euthanasia, use the word "euthanize" and avoid the use of the words "sacrifice" and "kill". Where practical, include sufficient detail and explanations to address anticipated questions and concerns from the general public.

Unacceptable Applications

Reasons why applications may not be accepted by the IACUC for review include, but are not limited to, the following:

- handwritten or incomplete applications;
 - use of an obsolete form;
 - unanswered questions;
 - principal investigator is not a member of the EMU faculty;
 - use of jargon in answering Questions 2, 3, and 4;
 - inadequate description of animal use procedures in Question 9;
 - excessive detail on non-animal procedures, such as lengthy descriptions of in vitro procedures performed on samples removed from euthanized animals;
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- insertion into the Application of complete or portions of grant applications in lieu of answering specific questions;
- a single composite answer to questions with multiple subparts, such as a single answer to both Questions 9a and 9b;
- missing signatures in Questions 20 (if applicable) and 21.

DETAILED INSTRUCTIONS

COVER PAGE

New Application

Check here if this research or instructional project has not been approved previously by the IACUC.

Renewal Application

Check here if this research or instructional project was approved previously by the IACUC, but is approaching the end of its IACUC approval period. Provide the previous Application/Approval Number and complete this application in full as if it were a new application.

Principal Investigator/Course Director

Provide the name of the Principal Investigator responsible for the research project or, in the case of a course, the Course Director. Only one principal investigator or course director can be listed per application.

Academic Rank/Title

The principal investigator must hold one of the following academic ranks: lecturer; instructor; assistant, associate, or full professor. Adjunct, emeritus, clinical, and visiting designations are also accepted.

Department/Unit Administering Accounts

Identify the department or unit that will manage the funds used to purchase animals and pay for animal care costs. Principal investigators holding joint appointments should list only the department or unit which will administer the accounts for this research project.

Mailing Address

Include room number and building.

Telephone/FAX/E-mail

Self-explanatory. If none, so indicate.

Other Contact Person(s)

Provide the names and telephone/FAX/E-mail numbers of persons familiar with this application who would be able to answer questions on behalf of the principal investigator.

Project/Course Titles and Funding Agencies

Enter the same title(s) as used on grant application(s). The IACUC application can accommodate multiple titles and multiple funding agencies. However, list only one corresponding title and funding

agency per space. If the same title is used for more than one agency, or the same agency is used for more than one title, repeat the title or agency as necessary. A separate approval letter will be generated for each title/agency combination provided. Add an additional sheet using the same format if more than three title/agency combinations are required.

Currently Funded?

Indicate the current funding status of each title/agency combination at the time this application is submitted to the IACUC.

Check "Yes" if the research project has been peer reviewed and is currently funded (list the reviewing agencies again in Question 19 and attach a copy of the award notice to this application).

Check "Yes" if the research project will use departmental or discretionary funds and the signature of the department chairperson or designate has been provided in Question 20.

Check "No" if the research project has not been peer reviewed and funded. Remember to forward a copy of the award notice to IACUC (Office of the Associate Provost) when the project is funded in order to activate approval.

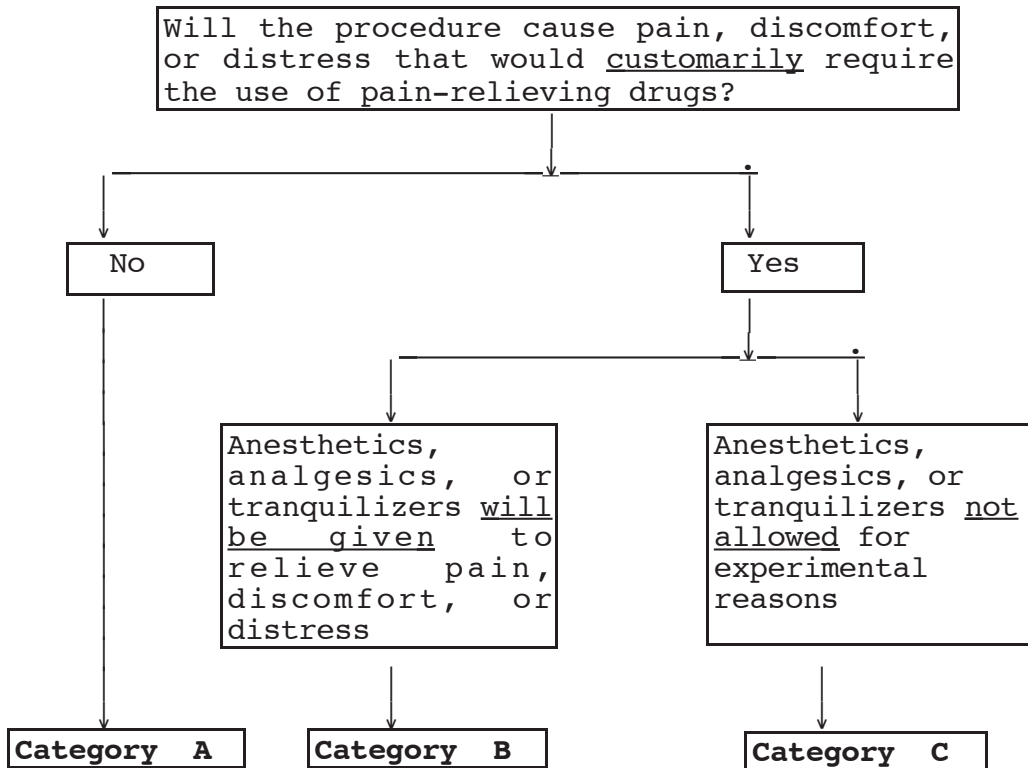
DESCRIPTION OF PROJECT (QUESTIONS 1 - 5)

- Question 1.** Check all that apply. This information will help reviewers to consider the application from the appropriate perspective.
- Question 2.** This question pertains to your broad global goals. What is the ultimate question that this research project will endeavor to answer? Because some members of the Committee are not scientists, write as if you were describing your research goals to your neighbor.
- Question 3.** This question pertains to your narrow specific aims. What are the specific objectives that you will attempt to accomplish with the animal studies described in this application? These may be the specific objectives in your grant application or the objectives of the animal component of a larger comprehensive project with both animal and non-animal components. Because some members of the Committee are not scientists, write as if you were describing the specific objectives to your neighbor.
- Question 4.** Be as specific as possible in explaining how this research might eventually impact the general society in a positive way. Because some members of the Committee are not scientists, write as if you were explaining this to your neighbor.
- Question 5.** Check all that apply. This information will assist reviewers as they read and interpret the descriptive portion of the application. It may also assist applicants in formulating their descriptive answers later in the application.

NUMBER OF ANIMALS, SPECIES AND HUMANE USE CATEGORIES (QUESTION 6)

Question 6. Estimate the maximum number of each species (use common name) required for this project during the 3-year application period. Apportion the numbers to the appropriate Humane Use Categories according to the definitions given in Question 6. The decision tree below may assist you in selecting the proper Humane Use Category.

IACUC HUMANE USE CATEGORY DECISION TREE



Category A animals are expected to experience either 1) no pain, discomfort, or distress at all or, 2) pain, discomfort, or distress that would not customarily be treated with pain-relieving drugs in human medicine or standard veterinary practice.

Category B animals are expected to experience pain, discomfort, or distress which would customarily be treated with anesthetics, analgesics, or tranquilizers,

and this treatment will be given as appropriate because it would not interfere with the experimental results or interpretation.

Category C animals are expected to experience pain, discomfort, or distress that would customarily be treated with anesthetics, analgesics, or tranquilizers, but the use of these drugs is prohibited by the research plan because their administration would interfere with the experimental results or interpretation.

Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings also cause pain or distress in other animals.

NOTE: If there are animals in Category C, attach to this application, on a separate page, a description of the procedures producing pain, discomfort or distress in animals and the reasons anesthetics, analgesics, or tranquilizers cannot be used. This page will accompany the University's annual report to the United States Department of Agriculture and will be available to the public under the Federal Freedom of Information Act.

Examples of procedures typically classified in each Humane Use Category are given below:

Category A: antibody production, ascites production, breeding, euthanasia without prior experimental procedures, tissue harvest after euthanasia, oral gavage, IV/IP/SC injections, irradiation, observation, radiography;

Category B non-recovery surgery, skin biopsy, intracardiac injection, vascular cutdowns, burn, laparotomy, thoracotomy, debilitating tumor growth, myocardial infarction;

Category C: any Category B procedure for which the customary administration of pain-relieving drugs is prohibited because it would adversely affect the results or interpretation of the studies (e.g., studies of pain, some toxicity tests, etc.).

Please note that the examples provided above are typical at best. Actual classification will depend upon the particular circumstances of the procedures performed.

ANESTHETIC, ANALGESIC, TRANQUILIZING OR NEUROMUSCULAR BLOCKING AGENT(S) AND POST-ANESTHETIC RECOVERY (QUESTIONS 7a - 7L)

Question 7a. Self-explanatory.

Question 7b. Provide the following information for each anesthetic, analgesic, tranquilizer, and neuromuscular blocking agent you propose to use. If more than four agents will be used, duplicate the table to accommodate additional entries.

Agent: List generic or trade name. For example, ketamine. Include agents used before animals are

euthanized, but do not include agents used for euthanasia only.

Species: List the common name of the animal that will be given the drug. For example, cat.

Dose: Provide the amount of drug to be given per unit of body weight. For example, 20 mg/kg.

Route of administration: By what route will the drug be given? For example, intravenous (IV), intramuscular (IM), subcutaneous (SC), etc.

Frequency of administration: Approximately how often will you administer the drug? For example, twice a day, every 60 minutes, or as needed.

Post-procedural administration: Will drugs be administered after the procedures described in Question 8? For example, will analgesics be given after surgery?

Question 7c. Self-explanatory.

Question 7d. Give maximum duration of anesthesia in minutes or hours.

Question 7e. What physiological parameters will you evaluate in order to monitor depth of anesthesia? For example, respiratory rate and character, blood pressure, heart rate, palpebral reflex, pedal withdrawal (toe pinch) reflex, etc.

Question 7f. What changes in the parameters listed in Question 6e will indicate that an anesthetized animal requires additional anesthetic? For example, increase in blood pressure, increase in heart rate, presence of pedal withdrawal (toe pinch) reflex, presence of palpebral reflex, etc.

Question 7g. Self-explanatory.

Question 7h. Self-explanatory. Standard operating procedures for postanesthetic and postsurgical medical care and records for animals are available from IACUC. Call 7-3277 to request copies.

Question 7i. Self-explanatory.

Question 7j. If analgesics will be administered postoperatively or postprocedurally, describe how you will evaluate whether an animal needs additional doses of pain-relieving drugs.

Question 7k. Self-explanatory.

Question 7l. If neuromuscular blocking agents will be administered, how will you determine that a paralyzed animal is unable to feel pain?

EUTHANASIA (QUESTIONS 8a - 8i)

Question 8a. Provide the following information regarding euthanasia of each species used. If more than four species will be used, duplicate the table to accommodate additional entries.

Species: List the common name of the animal that will be euthanized. For example, cat.

Method: List the proposed method of euthanasia. For example, anesthetic overdose, CO₂ overdose, cervical dislocation, decapitation, etc.

Agent (if applicable): List the generic or trade name of injected or inhaled euthanasia agents. For example, CO₂, sodium pentobarbital, etc.

Dose (if applicable): For injectable euthanasia agents, provide the amount of drug to be given per unit of body weight. For example, 100 mg/kg.

Route of administration (if applicable): By what route will the euthanasia agent be given? For example, intravenous (IV), intraperitoneal (IP), inhalation, etc.

AVMA Classification: Refer to the IACUC document, "Methods of Euthanasia by Species", adapted from the "Report of the AVMA Panel on Euthanasia". A copy of "Methods of Euthanasia by Species" is included on the floppy disk that contains the Application Form. Call IACUC at the Office of the Associate Provost at 487-3277 to request a complete copy of the "Report of the AVMA Panel on Euthanasia" or the IACUC document, "Methods of Euthanasia by Species".

Question 8b. Self-explanatory.

Question 8c. If the method of euthanasia you have selected is classified in the chart, "Methods of Euthanasia by Species", as either conditionally acceptable (CA) or unacceptable (U), explain why this method must be used to accomplish the objectives of this research project and why an acceptable method cannot be used. If you have selected a method classified as acceptable, no explanation need be given.

Question 8d. What measures will you employ to ensure that an animal that has been euthanized will not spontaneously recover. For example, if a drug overdose has been given, a pneumothorax could be induced to ensure that spontaneous recovery is impossible. If the method chosen itself ensures that the animal cannot recover (for example, decapitation), so indicate.

Question 8e. Self-explanatory.

Question 8f. If some animals will not be euthanized at the end of the studies, indicate what will happen to those animals. Intra-university transfer of animals requires completion and submission of "Transfer or Sale of Research Animals" form, available from IACUC at the Office of the Associate Provost, 487-3277.

Question 8g. Self-explanatory.

Question 8h. Self-explanatory.

Question 8i. Self-explanatory

ANIMAL USE PROCEDURES AND FACILITIES (QUESTIONS 9)

Question 9. Describe in narrative form the animal use procedures in the order in which they will be performed. Link the procedures to the specific objectives described in Question 3. Include time frames and intervals between procedures, as well as drugs and test substances administered to the animals. Also describe procedures performed on anesthetized animals. Your answer to this question will provide reviewers with a context in which to review information provided elsewhere in the application. It is not necessary to describe in vitro procedures performed on tissues taken from animals or procedures performed on animals after they are euthanized.

ADVERSE CONSEQUENCES (QUESTIONS 9a - 9b)

Question 9a. This question is intended to ascertain the ethical cost of this project. In this context, the ethical cost refers to animal distress, discomfort, pain, and loss of animal life including euthanasia. Its three-fold purpose is to (1) sensitize investigators to the ethical cost, (2) inform reviewers of the ethical cost, and (3) assure the general public that both the investigator and IACUC reviewers have considered the ethical cost of this project. Expected adverse consequences are those that are likely to occur as a result of the procedures described in Question 9. If the project involves the death or euthanasia of animals, be sure to include loss of animal life in your description of expected adverse consequences.

Question 9b. This question also pertains to the ethical cost of this project. List severe complications that might occur (even if unlikely) as a result of the procedures described in Question 9.

Question 9c. Discuss the reasons for using animals to obtain the information you seek. Can the objectives discussed in Question 3 be achieved without the use of animals? If yes, explain why you are proposing to use animals. If no, explain how the use of animals will enable you to meet the objectives.

Question 9d. Discuss the appropriateness of the animal model. Why was it selected over other animal models, particularly those utilizing species which might be perceived as lower on the evolutionary scale? Explain important biological characteristics of and your experience with the model.

Question 9e. In Question 6, you estimated the required number of each species in each Humane Use Category. Relate these estimates to the experimental design by apportioning the animal numbers obtained or generated for this research enterprise, including excess or unwanted progeny, excess or inadvertently captured animals, unusable animals, etc. Show how these estimates were calculated. The use of

outlines, tables and charts rather than text will facilitate review of this answer. Do not provide a detailed description of experimental and control groups. Avoid expressing the numbers of animals requested as a rate of usage (2 rats/week x 52 = 312 requested) unless the rate of usage is required by the experimental design (in vivo cell line passage, etc.) rather than by the capacity of the laboratory. Explain the answer to the question: What is the minimum number of animals required to answer this scientific question?

Principal investigators can obtain assistance in determining appropriate sample sizes from:

The Center for Research Support
Stuart Karabenick, Director
Learning Resources and Technologies
487-2254

Question 9f. Check all that apply and provide the additional information.

NOTE: Information regarding potential alternatives is available from:

The Animal Welfare Information Center
National Agricultural Library
Beltsville, MD 20705
301-504-6212

A bibliography published by the Center is available from IACUC in the Office of the Associate Provost.

SURGICAL PROCEDURES (QUESTION 10)

If the answer is yes, proceed to Appendix A

RESTRAINT (QUESTIONS 11a - 11d)

Question 11a. Self-explanatory.

Some examples of restraint devices include tethers, stanchions, tubes, sacks, slings, chairs, squeeze chutes, etc. Regulation sized housing enclosures such as cages and pens are not considered forms of restraint for traditional laboratory animals, whereas live trapping of wild animals would be considered restraint.

Question 11b. Self-explanatory. See examples in Question 11a.

Question 11c. For example: 2 hours of restraint each week.

Question 11d. The "Guide for the Care and Use of Laboratory Animals" provides the following guidelines for the use of restraint equipment: (1) animals to be placed in restraint equipment should be conditioned to such equipment prior to initiation of research; (2) the period of restraint should be the minimum required to accomplish the research objectives; (3) restraint chairs, or similar devices are not to be considered

"normal" methods of housing; (4) restraint chairs or similar devices must not be used simply as a convenience to investigators in handling or managing animals; and (5) attention must be paid to the possible development of lesions or illnesses associated with restraint.

Explain why animals must be restrained for a prolonged period of time. Why couldn't the same research results be obtained by restraining animals intermittently or chemically?

BREEDING COLONIES (QUESTION 12) Self-explanatory

ACQUISITION, QUARANTINE, CONDITIONING, ANIMAL HEALTH, ANIMAL HOUSING AND ANIMAL USE FACILITIES (QUESTIONS 13 -14)

Question 13. All purchase requisitions for animals will be placed through the Central Purchasing and require the signature of the Chairman of ICUCA, or designate. Note if animals are to be acquired by other means than with a University Purchase Order or intra-university transfer (e.g., donation, capture, in-house breeding, etc.). If animals will be obtained from the wild, identify the location where they will be captured.

Question 14. For this project only, list all rooms where experimental or instructional procedures described in Question 9 will be performed on animals. For each room, list the species that will be used in that room. For each combination of procedure room and species, answer the questions regarding the procedures that will be performed in that room. Answer the first two questions for all species requested, the next question if you will be performing procedures on rodents, birds, fish, amphibians, or reptiles, and the last three if you will be performing procedures on non-rodent mammals. If procedures will be performed in an animal room and you do not know where your animals will be housed yet, write "To be determined" in the "Room Number" cell.

Note: If you will need to use the surgical facility, you must make arrangements directly with the Mark Jefferson Animal Facility supervisor.

Room Number: List the number of the room where procedures will be performed.

Building: List the building name.

Species: List the common name of the animal that will be used. For example, cat.

Non-surgical animal procedures: Answer "Yes" if the procedure does not involve any type of surgical intervention.

Laboratory housing for more than 12 hours: Answer "Yes" if live animals will be held in the laboratory for more than 12 hours. Answer "Not Applicable" if procedures are conducted in an animal housing room.

Recovery surgical procedures performed on rodents, birds, fish, amphibians, or reptiles: Answer "Yes" if minor or major surgery is performed on rodents, birds, fish, amphibians, or reptiles and the animal is permitted to survive following surgery. Commonly used rodents include rats, mice, guinea pigs, hamsters, gerbils, and chinchillas. Rabbits are not rodents.

Major non-recovery surgical procedures: Answer "Yes" if the animal is not permitted to survive following surgery and 1) the procedure is a surgical intervention that will penetrate and expose a body cavity or 2) the procedure would produce permanent impairment of physical or physiological functions.

Minor recovery surgical procedures: Answer "Yes" if the animal is permitted to survive following surgery and 1) the procedure is a surgical intervention that does not penetrate and expose a body cavity or 2) the procedure will not produce permanent impairment of physical or physiological functions. Examples would include vascular cutdowns and subcutaneous implantation of a device.

Major recovery surgical procedures: Answer "Yes" if the animal is permitted to survive following surgery and 1) the procedure is a surgical intervention that will penetrate and expose a body cavity or 2) the procedure will produce permanent impairment of physical or physiological functions. Examples would include thoracotomy, laparotomy, and hypophysectomy.

BIOHAZARD USE Question 15.

Self-explanatory. This question pertains to agents that may present a hazard to humans or other animals in the animal housing facility or contiguous procedure rooms. Do not include hazards that will be present only in the research laboratory.

PERSONNEL (QUESTIONS 16, 17 and 18)

Question 16. Self-explanatory

Question 17. List training personnel and their qualifications. Trainers should be capable of providing training to animal use personnel on the following topics: normal animal behavior; signs of injury, illness, or disease; reporting ill or injured animals to the animal technician; pertinent animal use techniques; and occupational health and safety concerns pertaining to animal use in research.

This does not mean that training can be provided at the time you begin your studies. Arrangements for training must be made directly with the IACUC Office in advance of your requirement. To arrange for training, contact the IACUC at 7-3277. Self-explanatory

Question 18. List all personnel who will have contact with research animals, including those who will perform the

experimental procedures, as well as all personnel listed in the answers to Appendices A and B.. Contact with research animals includes entering animal rooms or laboratories where animals are held as well as handling them. Only personnel averaging less than 8 hours a week contact with small animals (i.e., birds, rodents, rabbits, fish, amphibians, and reptiles) are exempt from participation in the EMU Health Program for Animal Handlers, which is administered by the EMU Snow Health Center. All other personnel who contact animals must participate.

APPROVAL OF SCIENTIFIC MERIT

- Question 19.** List reviewing agencies. Applications will be considered funded only if accompanied by a copy of the award notice.
- Question 20.** Check the type of departmental review utilized. If you check "Other", describe the review process. Contact IACUC at 487-3277 for a list of Official Designates for your department, or for information on an alternative system of internal review for scientific merit.

PRINCIPAL INVESTIGATOR'S ASSURANCE

Read and sign the Assurance Statement. A copy of the "EMU Principles for the Care and Use of Laboratory Animals" is included on the floppy disk that contains the Application Form.

INSTRUCTIONS FOR COMPLETING APPENDIX A

- Question A1.** Also include the names of these persons in the answer to Question 16.
- Question A2.** Animal surgical facilities must be IACUC-approved.

Describe the physical location where surgery is performed. Rodent surgery does not require use of a dedicated operating room. It does require use of a room or portion of a room that is easily sanitized and not used for any other purpose during the time of surgery. For detailed information on rodent surgery consult the "EMU Guidelines for the Performance of Survival Surgery on Rodents", available from IACUC at the Office of the Associate Provost (487-3277).

- Question A3.** Surgical instruments must be sterilized before use in survival rodent surgery. Although the use of sterile instruments is highly desirable for all survival surgical procedures, it may not be feasible under circumstances where many surgical procedures will be performed in a single session. Under these circumstances, investigators should begin with at least 2 sets of sterile instruments. After the sterile instruments have been used, they should be thoroughly

cleaned to remove all organic material (and dried, if possible), then treated with a high-level disinfectant - at an appropriate concentration and for an appropriate length of time - before being used on the next animal. Starting with an adequate number of sterile sets will enable the surgeon to continue to work while used instruments are being disinfected. For detailed information on rodent surgery consult the "EMU Guidelines for the Performance of Survival Surgery on Rodents", available from the IACUC (487-3277).

- Question A4.** Preparation of a rodent for surgery requires attention to both the specific surgical site and the physiological status of the entire animal. Particular attention should be paid to maintenance of the animal's body temperature. Hair must be removed from the area surrounding the proposed site of the surgical incision. The next step is to clean and disinfect the animal's skin using an appropriate scrubbing technique (e.g., vigorous scrubbing in gradually enlarging circular pattern) and an effective disinfectant. After disinfection of the skin, the animal should be covered with a sterile drape with a fenestration over the proposed incision site. For detailed information on rodent surgery consult the "EMU Guidelines for the Performance of Survival Surgery on Rodents", available from the IACUC (487-3277).
- Question A5.** Ideally, the surgeon should scrub hands and arms with a disinfectant soap and wear shoe covers, cap, mask, and sterile gown and gloves. While all of this may be a bit impractical for rodent surgery, surgeons should at least wash hands before surgery and wear a mask and sterile gloves. A clean scrub shirt or lab coat may be worn in lieu of a sterile gown. A new pair of sterile gloves should be worn for each animal, even if many animals will be operated on in a single session. For detailed information on rodent surgery consult the "EMU Guidelines for the Performance of Survival Surgery on Rodents", available from the IACUC (487-3277).
- Question A6.** A major recovery surgical procedure is any surgical intervention from which the animal is permitted to survive following surgery and that 1) will penetrate and expose a body cavity or 2) produce permanent impairment of physical or physiological functions. Examples would include thoracotomy, laparotomy, and hypophysectomy. "Multiple major recovery surgical procedures" mean that the animal(s) will recover from at least two major surgical procedures.
- Question A7.** List, but do not describe (the description should have been included in the answer to Question 9), the recovery surgical procedures in the order in which they will be performed on the animal.
- Question A8.** What will be the minimum length of time an animal will be allowed to survive following one major surgical

procedure before undergoing the next major surgical procedure?

Question A9. According to the Animal Welfare Act regulations: "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (A) Justified for scientific reasons by the principal investigator, in writing; (B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or (C) In other special circumstances as determined by the Administrator [of the Animal and Plant Health Inspection Service, United States Department of Agriculture] on an individual basis." What are the scientific reasons for performing multiple major survival surgical procedures on individual animals? Why must animals recover from the second or subsequent surgical procedure? Why couldn't the same research results be achieved by performing surgical procedures on separate animals?

Questions A9 & 10. A major recovery surgical procedure is any surgical intervention from which the animal is permitted to survive following surgery and that 1) will penetrate and expose a body cavity or 2) produce permanent impairment of physical or physiological functions.

Refer to the instructions for Question 9A for information on the Animal Welfare Act regulations regarding multiple recovery surgical procedures. What are the scientific reasons for performing additional major survival surgical procedures on animals that have undergone major surgery in another project?

INSTRUCTIONS FOR APPENDIX B

Question B1. Provide the following information for each hazardous agent used. If more than four agents are used, duplicate the table to accommodate additional entries.

Hazardous agent: Provide the name of the agent.

Type of hazard: Classify the hazard as infectious, carcinogenic, radioactive, toxic, or chemical.

Amount administered: What is the largest quantity that will be given to each animal?

Route of administration: By what route will the hazardous agent be given? For example, intravenous (IV), intraperitoneal (IP), inhalation, etc.

Duration/frequency of exposure of animals: How long and/or how often will animals be exposed to the agent?

Duration of hazard in animal facility: After an individual animal has been given the hazard, how long will the hazard be present in the animal facility such that humans or other animals might be exposed to it?

Question B2. Self-explanatory.

Question B3. Self-explanatory.

Question B4. Contact the Radiation Control Officer for a copy of "Standard Procedures and Protocols for Using Radioactive Material in Animals". If "No", attach a copy of the protocols to be used to prevent exposure of personnel and other animals to radioactive materials.

Question B5. Self-explanatory. If "Yes", attach a copy of the protocols to be used to prevent exposure of personnel and other animals to carcinogenic, toxic, or chemical hazards. Note that standard protocols are not maintained by IACUC because such protocols must be tailored to the specific agent(s) being used. Contact the IACUC at 487-3277 for assistance in preparing containment protocols for these types of agents.