Basic Training Module for Research Personnel
Welcome to the IU Bloomington (IUB) Training Program in Laboratory Animal Care and Use. This Basic Module for Research Personnel is required for all faculty, staff, and students who use laboratory animals in research, teaching or training. If you are designated as a participant in an IUB animal use protocol, you must complete this module as part of the IACUC approval of that protocol. It is composed of the following 15 sections:

1. Regulations and Principles Related to Laboratory Animal Use
2. Institutional Animal Care and Use Committee
3. Division of Animal Resources
4. Campus Policies Related to Laboratory Animal Use
5. PI Responsibilities in Identifying and Training Laboratory Personnel
6. Research Requiring Registration with the Biological Safety Committee
7. Protocol Preparation, Submission and the Review/Approval Process
8. Amending Animal Use Protocols
9. Alternatives to Painful Procedures: Database Searches
10. The IUB Occupational Health and Safety Program
11. Procurement, Transfer, and Transport of Laboratory Animals
12. Evaluating Pain and Distress in Laboratory Animals
13. Veterinary Care: Reporting Sick, Injured or Dead Animals
14. Quarantine and Isolation of Animals
15. Reporting of Animal Welfare Concerns and/or Animal Care and Treatment Deficiencies

After reviewing the material in these 15 sections, you must answer 17 or more of the 20 questions correctly at http://www.srs.indiana.edu/LARTest/LARTest.asp?SN=1.
Section 1

Regulations and Principles Related to Laboratory Animal Use

There are federal regulations and campus policies governing all use of vertebrate animals in research or instruction activities conducted at or sponsored by Indiana University Bloomington (IUB). All faculty, students, staff, visitors and volunteers who participate in research, teaching and/or testing using animals at IUB must adhere to these standards.

IUB is registered with the Secretary of Agriculture as a research facility in accordance with the Animal Welfare Act. In addition, in accordance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals, the University maintains an animal welfare assurance with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health. The President is the chief executive officer and serves as the institutional official. Responsibility for assuring compliance with state and federal laws and regulations has been delegated to the Vice Provost for Research.

Animal use conducted at or sponsored by the Bloomington Animal Care and Use Committee (BIACUC) must:

- Be in compliance with the Animal Welfare Act; the Public Health Service Policy on Humane Care and Use of Laboratory Animals; the U.S. Government Principles for the Utilization Care of Vertebrate Animals Used in Testing, Research, and Training; the Guide for the Care and Use of Laboratory Animals; and the Guide for the Care and Use of Agricultural Animals in Agricultural Research and teaching.

- Adhere to University policy and procedures administered through the Office of the Vice Provost for Research, such as the university's policy on research integrity (http://www.research.iu.edu/rschcomp/misconduct.html)

- Adhere to policies and procedures adopted by the Institutional Animal Care and Use Committee (IACUC)

The responsibilities of faculty and other investigators using animals in research or teaching include the obligations

- To become knowledgeable about and conduct all research and inquiry in accordance with approved policies governing the care and use of laboratory animals.

- To ensure that all research, teaching or testing using vertebrate animals in projects affiliated with Indiana University has been approved by the IACUC prior to initiation, irrespective of funding source.

- To submit animal care and use protocols, amendments, and updates for use as needed by the IACUC and as required by campus policy.

- To maintain complete records of procedures undertaken during all animal experiments.
• To use animals in approved animal care unit facilities. Where research protocols dictate unusual environmental, dietary, or colony requirements that cannot be met in approved animal care unit facilities, faculty must advise the campus IACUC and Laboratory Animal Resources (LAR) in advance of the proposed animal use activity. Animal housing outside approved animal units must be inspected or otherwise approved by the committee prior to use.

• To maintain a scholarly, sensitive, and respectful environment during all animal experimentation.

• To participate in continuing education and training programs designed to keep investigators abreast of the latest regulations and procedures in animal research.

• To emphasize the role of laboratory animals when presenting research results or discussing human diseases with lay audiences and describe the contributions of humanely conducted animal studies to the development of new technologies and treatment capabilities.

Regulatory Links


The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals was created to implement the Health Research Extension Act. The Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health enforces the Policy. OLAW provides specific guidance, instruction, and materials to institutions that must comply with PHS Policy. Their website is http://grants.nih.gov/grants/olaw/olaw.htm.

In general, PHS Policy requires adherence to The Guide for the Care and Use of Laboratory Animals. Principal investigators with animal use protocols approved by the BIACUC may request copies of the Guide by contacting the IACUC (iacuc@iindiana.edu). This document is available on-line at http://books.nap.edu/books/0309053773/html/.

The Federation of Animal Science Societies produces the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Experts in agricultural husbandry have contributed information based on current research and best practices to create a set of guidelines, which are generally accepted by the USDA, and other agencies evaluating the quality of agricultural animal care programs. The IACUC evaluates animal care and use protocols involving agricultural animals based on this "Ag Guide." The Federation of Animal Science Societies can be contacted at http://www.fass.org.
Section 2

Institutional Animal Care and Use Committee

The campus Institutional Animal Care and Use Committee (IACUC) is appointed by the President and advises the Vice Provost for Research in matters of animal care and use in research and teaching. The membership of the IACUC meets the requirements of federal laws and will include members who are qualified through experience and expertise. The IACUC membership includes veterinarians, nonscientists, at least one public member who is not affiliated with the University and represents general community interests in the care and use of animals. The majority of committee members are practicing scientists experienced in research using animals. Current IACUC membership includes Byron Bangert (bbangert@indiana.edu), John Foley (gfoley@indiana.edu), Tim Greives (tjgreive@indiana.edu), and Ellen Ketterson, Chair (ketterson@indiana.edu), Curt Lively (clively@indiana.edu), Ted Lock (t-lock@uiuc.edu), John Meredith West (mewest@indiana.edu), Randall Peper (lardir@indiana.edu), Randalyn Shepherd (iubdvm@indiana.edu), Suresh Viswanathan (suviswan@indiana.edu), and David Williams (williamd@indiana.edu).

The functions and authority of the Institutional Animal Care and Use Committee include:

- Reviewing the institution's program for humane care and use of animals semiannually.
- Inspecting all of the institution's animal facilities, including animal use areas, semiannually.
- Reviewing concerns involving the care and use of animals at the institution.
- Making written recommendations to the Vice Provost for Research regarding any aspect of the institution's animal program, facilities, or personnel training.
- Reviewing, approving, requiring modifications in (to secure approval), or withholding approval of animal use protocols as required by federal regulations.
- Reviewing, approving, requiring modifications in (to secure approval), or withholding approval of proposed significant changes regarding the use of animals in ongoing activities as required by federal regulations.
- Notifying investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as required by federal regulations.
- Suspending, as may be required, any activity involving animals that is not being conducted within provisions of federal law or campus policy.

All proposed animal use involving vertebrate animals to be conducted at or sponsored by IUB must be submitted for prior IACUC review and approval, and periodic review after approval in accordance with campus policies and federal regulations. Review of animal use protocols may be subject to further appropriate review and approval by officials of the University. These officials may not, however, approve an activity involving the care and use of animals if it has not been approved by the IACUC.
Section 3

Laboratory Animal Resources

Laboratory Animal Resources (LAR) was established as an administrative unit of the Vice Provost for Research to facilitate implementation of policy and to provide professional skills and services to the campus. LAR serves all animal units and animal users at IUB. LAR works in conjunction with the IACUC to ensure an effective animal care and use program for IUB.

LAR assures compliance with the applicable standards, laws, and regulations by overseeing programs of animal care through the animal care units. In addition, LAR directly manages the laboratory animal facilities on campus which are located at:

• School of Optometry, LAR, Jordan Hall, Psychological and Brain Sciences, and other approved locations

LAR is responsible for assuring that the care of animals used in research and teaching is professionally sound and that high standards of humane treatment of animals are observed. The functions and authority of LAR include:

- Working closely with the Vice Provost for Research, College Deans, and the IACUC to provide ongoing and strong leadership for the campus animal care and use program.
- Advising the administration, faculty, and animal care units with regard to regulations, guidelines, and professional standards pertaining to animal care and use, including providing guidance and expertise regarding proper animal environment, housing and management, physical plant and biosafety.
- Interpreting and aiding compliance with all federal and state laws, regulations, policies, and guidelines concerning the utilization of animals in research and teaching activities.
- Acting as a liaison with the Office of the Vice Provost for Research, the IACUC, and regulatory, funding, and accreditation agencies concerning animal welfare and use activities.
- Providing high quality care and promoting health and well being of animals used for research and teaching, which includes the assurance of appropriate veterinary care consistent with regulatory and accreditation expectations. Providing training programs for campus faculty, staff and students involved in the care and use of agricultural and laboratory animals as required by federal law.
Section 4

Campus Policies Related to Laboratory Animal Use

- The IUB Institutional Animal Care and Use Committee (BIACUC) establishes campus policies related to use of animals in order to assist investigators and animal care staff in interpreting existing regulations and guidelines, to assure compliance with existing regulations, and to provide public assurance of humane treatment of laboratory animals. As policies are established or revised, they will be posted on the Institutional Animal Care and Use Committee's (IACUC) web site.

All research personnel involved in protocols using animals are expected to be knowledgeable about these policies and incorporate their requirements into animal use protocols. In order to complete this module, please find and review these policies before attempting to answer the questions at the completion of the Basic Module for Research Personnel. Some of the material described in these policies will be described in subsequent sections of this training module.
Section 5
PI Responsibilities in Identifying and Training Laboratory Personnel

When submitting an animal use protocol for review, the PI should be sure that three duties are fulfilled in regard to project personnel.

1) The Principal Investigator (PI), as project director, must submit names, training, and experience of all personnel involved in experiments, instruction, testing or other procedures described in an animal use protocol. The PI must provide assurance on the animal use protocol that all personnel involved in the projects described are adequately trained to perform all procedures involving animals. The description for each person, including the PI, should include the specific role(s) he or she will perform, and the person’s experience or training with each procedure. In cases in which the PI does not work directly with the animals, s/he must be included, nevertheless, so that the IACUC can determine that the PI has the ability to oversee he project and provide adequate training and guidance.

2) In addition, the PI is responsible for informing all project personnel of the required participation in the OHS Program. The IACUC Office will not approve a protocol unless all personnel are participants. All participants will receive educational fact sheets concerning their exposure risks. The PI is responsible for providing training for all animal procedures and providing personal protection equipment. To enroll in the program, please go to the OHS web site at http://www.indiana.edu/~lar/ohs/

All faculty, staff and students with animal exposure have the opportunity to participate in the health screening program. Screening is available at the IU health center on 10th Street. Contact the LAR office for more information.

The PI will receive information from the IACUC and/or the IU Health Center about the hazards that personnel are exposed to, and how to protect personnel. This information must be provided to all personnel receiving the exposures. In addition, all faculty, staff, and students working with animals and/or animal products on the IUB campus must be offered the opportunity to participate in a medical screening program. The screening is available at no cost. Individuals with allergies, or those working with infectious disease organisms, for example, should seriously consider taking part in the surveillance program. Questions may be directed to LAR.

3) All project personnel whose names are listed on an animal use protocol must be registered in the On-line Training Program for Research Personnel. In order to register, project personnel must complete the questions at the end of this Basic Training Module. If further training is requested by the IACUC, this must be documented before personnel may participate in an approved protocol.

Principal investigators are strongly encouraged to have all new personnel involved in animal use protocols enroll in the OHS Program and ask them to review the on-line training module and take the quiz as soon as they join the lab. This will prevent delays in protocol approval should they be listed as project personnel. No personnel will be permitted to participate in an animal use protocol until these requirements are met.

4) Communicate to all personnel associated with a protocol when major changes in an experiment occur that affect handling or disposition of the animals, such as infection or treatment.
Section 6
Research Requiring Authorization by the Office of Research Safety

The Office of Research Safety serves as the institutional biosafety committee for Indiana University, as required by the NIH Guidelines for Research Involving Recombinant DNA Molecules. As per the NIH Guidelines and University-policy, registration with the IBC is required for animal users whose work involves any of the following:

- Human materials (e.g., human cell lines; blood or blood products; semen or vaginal secretions; fluids surrounding internal organs, the joints or a fetus; any body fluids contaminated with visible blood; any tissues)
- Any plant, animal or human pathogen
- Transgenic animals (use or creation), including “knock-outs”
- Transgenic plants
- Nonhuman primate materials
- Biotoxins
- Wild mammal materials
- Recombinant DNA (including work that may be considered “exempt” from the NIH Guidelines must be registered*)

* The University is responsible for ensuring that all recombinant DNA research, irrespective of funding source, is conducted “in full conformity with the provisions of the NIH Guidelines”. In order ensure compliance with the Guidelines, University Policy requires that all recombinant DNA work must be registered with the IBC. Penalties for University/Principal Investigator noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for rDNA research at the university, or (ii) a requirement for prior NIH approval of any or all rDNA projects at the University.

IACUC approval is contingent upon Biosafety approval where applicable. You must register your research project with the IBC to initiate the approval process. The Biological Safety Section (BSS) of the Division of Research Safety (DRS) coordinates project registration. Registration forms and additional information about the registration process may be obtained on the DRS website at: http://research.iu.edu/rschcomp/rschsafety/index.html If you have previously registered your project, you are required to update registration information whenever there are changes in the facilities, personnel, and experimental protocols associated with the project.

Disposal of Experimental Animals

Pathological waste includes animal carcasses, tissues and organs. University policy requires certain types of pathological waste be disposed of by incineration.
All of the following animals and tissues or organs from these animals must be incinerated:  
• Any animal inoculated with infectious agents  
• Transgenic animals, potentially transgenic animals, “no-takes” in the production of transgenic animals, and off-spring of transgenic animals.  
• Small research animals (e.g., cats, dogs, rabbits, rats, mice).

There are no exceptions to this policy without prior notification and approval by the Institutional Biosafety Committee.

Any incident involving inadvertent release or improper disposal of biohazardous or recombinant DNA materials, including transgenic animals, must be reported immediately to the Institutional Biosafety Committee via the Biological Safety Section (BSS) of the Division of Research Safety (DRS). BSS can be contacted at 856-3638 and bereeves@indiana.edu.
Section 7
Protocol Preparation, Submission and the Review/Approval Process

No research, teaching, or testing using vertebrate animals in projects affiliated with Indiana University may begin without an approved animal use protocol. To prepare and submit a protocol, follow these steps:

* Download the form from the IUB research compliance website http://research.iu.edu/rschcomp/animals.html

* Answer all questions completely.

* Answers must be typed and included in the body of the protocol form.

* Documents attached or references cited in lieu of answers to specific questions will not be accepted.

* "N/A" should be inserted for items that do not apply to a given protocol.

* Submit the completed form electronically to the IACUC (iacuc@indiana.edu)

* LAR staff can assist research personnel who have questions during preparation of a protocol.

Protocol Review and Approval (abbreviated)

* The protocol will be considered at the next monthly meeting of the IACUC

* Following discussion at the convened meeting, a protocol may receive approval, or the IACUC may require additional information from the PI before approval can be granted.

* The IACUC’s questions regarding the project are compiled and sent to the PI via e-mail.

* PI's are asked to respond within two weeks. Responses must include the questions and responses in the body of an e-mail, as well as being incorporated into the protocol.

* Failure to respond in a timely manner may result in termination of the review process. Delays by the PI in responding to questions impedes the approval process.

* The PI’s responses are distributed to the IACUC members who have 72 hours to ask additional questions, or call for full committee review of a protocol at the next convened monthly meeting.

* Approved protocols receive final approval when signed by the IACUC Chair and the Attending Veterinarian. The PI will receive written notification.

* PIs must adhere to all aspects of the protocol as approved, i.e., including any changes introduced during the approval process. They need to maintain copies of the protocol in its finally approved form and keep all project participants fully informed of all procedures and any procedural changes, and inform the IACUC, via submission of an amendment request, before any changes in procedure, personnel, etc. are implemented.
* Principal Investigators who submit protocols for which approval is denied may resubmit a revised protocol for reconsideration.

* Note: Protocols including certain critical procedures, even if scientifically justified, such as unrelieved pain, prolonged restraint, multiple major survival surgeries, or death as an endpoint, will receive utmost scrutiny.

Protocol review and approval (in more detail)

The investigator or teacher must fill out a BIACUC Animal Care and Use Application for each project (see definition below) using animals and submit it to the Departmental Animal Care Committee. The application must supply the following information:

1. The species and number of animals used along with a rationale for using animals, and for the appropriateness of the species and numbers to be used.

2. The anticipated source of the animals (e.g., commercial breeder, live trapping, local breeding colony), whether quarantine will be required, the location(s) of housing and use, and the dates of proposed use.

3. A description of the relevant details of all procedures involving the animals. Be sure to list methods of anesthesia including drug(s), dosage, and route of administration, any requirements for analgesia and post-operative care, and the method of euthanasia for each species, again including name of agent, dosage, and route of administration.

4. Information concerning granting agencies and grant titles, and a way to reach the investigator.

5. The application should be sent in electronic form to the IACUC (iacuc@indiana.edu) or to LAR in care of IACUC Administration, 819 N. Forrest Ave., Room 101, Indiana University, Bloomington). The IACUC Administrator will assign a protocol number, log the proposal, and place it on the agenda for the next BIACUC meeting. The agenda for the committee will be sent to all members of BIACUC prior to each scheduled meeting.

6. At a BIACUC meeting, proposals on the agenda can be approved, not approved pending further information, declined with explanation, or tabled. The investigator will be informed by e-mail of the IACUC’s action within a few days. In the case of an externally funded application that has already been submitted, the IACUC administrator can inform the appropriate agency of BIACUC approval if requested. If the protocol is declined, the investigator must begin the submission process again. If the protocol requires modification, the Chairperson of BIACUC or an appropriate substitute committee member selected by the Chair, may approve an appropriately amended protocol prior to the next meeting, unless any member of the IACUC objects in which case it can be placed on the agenda for the next meeting of BIACUC.

Please note the following regarding terminology. A ‘project’ is defined as a single academic course, or as a set of similar experiments such as might be found in a grant proposal. The critical aspect of defining a set of experiments as a project is that all aspects of procedures, care, justification of species and number, and euthanasia are readily dealt with on a single Animal Care and Use application. Any alteration in responses to the checklist on the application form, or significant change in the justification or approximate number of animals used requires the filing of an amendment, or, if there is substantial alteration, the filing of a new application. It should be clear that the more similar the experiments are in basic scientific procedures, the
more reasonable it will be to include them in a project application. However, with appropriate justification, diverse procedures can be included in the same project.

Each application will be assigned a Protocol Number. This number should be retained and referred to in correspondence with the committee. In addition this number should be used in reporting animals ordered.

Animal Care and Use Applications should be filed in good time prior to the anticipated start of a teaching or research activity. In order for an Application to be reviewed during a specific monthly meeting, it must be received by the IACUC administrator by the fifteenth (15th) of the month. The Bloomington campus internal review process is currently set-up so that it takes a minimum of about two weeks and a maximum of about six weeks for a protocol to be reviewed. Please be sure to allow sufficient time to process your paperwork.

Animal Care and Use approvals must be kept current. A change in procedures, species, or number of animals must be accompanied by an amendment or a new Animal Care and Use application depending on the degree of change.

Amendments are required if there is any change in the Animal Care and Use Application for a particular project. The form for amendments may be found on line, [http://research.iu.edu/rschcomp/animals.html](http://research.iu.edu/rschcomp/animals.html)

BIACUC is mandated to give continuing protocols an annual review. BIACUC will remind the investigator that a review is forthcoming, and the investigator is expected to inform BIACUC promptly either that the same protocol is still in effect, or submit to BIACUC appropriate amendments, cancellations, or new protocols.

In order to ensure a high probability that your vertebrate animal care and use approval will go in with your grant, BIACUC has the following recommendations:

When submitting a new grant or a competing renewal, be aware that we try to ensure that one BIACUC meeting is sufficient for evaluating most protocols, but the interests of the PI are best served by allowing time for two meetings, and quickly replying to all requests for information.

The IACUC may invite consultants to present views and information. The consultants may not remain during deliberations or any other part of the meetings.

A final reminder: Research and teaching involving animals on the Bloomington Campus must not take place until BIACUC approval has been secured. BIACUC has no choice but to suspend research and teaching that is conducted without approval and to refer the matter to the appropriate institutional official for permanent disposition and any sanctions.
Section 8
Amending Animal Use Protocols

Any change in a project involving animals requires additional review by the Institutional Animal Care and Use Committee (IACUC) or staff, and may not be undertaken until approval has been granted. Changes may be either minor or significant.

Amendments that may be expedited

- Change in project title or Funding source
- Addition or removal of project personnel
- Addition of new animal genetic background or strain, where change does not include new transgenic strains or impact animal care. A change from rodents to dogs would not be considered minor.
- Increase in number of animals; additions are limited to $\leq 10\%$ of number originally approved for each species at a given time.
- Change in animal care facility, housing unit or field site to other approved location.
- Change in administration of experiment/treatment as it relates to timing, dose, route of administration and/or specific chemical composition, where change does not alter the invasiveness of the procedure, specific objective(s), or scientific rationale.
- Change in manner of disposition of animals at the end of the study.

To make the above changes you must file an amendment signed by the PI(s). Note that even minor amendments must be complete and their relation to the approved protocol must be explicit and readily understood. All changes must be fully described and justified. Experience and/or training of new personnel in the procedures they are to perform must be described.

Significant amendments requiring assessment by the convened IACUC

Permission for more substantial changes to a protocol must also be submitted on the amendment form but will require fuller justification and more time to process. The amendment must reference by number and title the protocol to be amended, and provide a summary and justification for all requested changes. Submissions must include sufficient information for the IACUC to evaluate changes using the same criteria as in the initial review.

All changes must be fully described and justified. For instance, if a surgical procedure is to be added, the request must describe pre- and post-operative care of the animal; preparation of the surgeon, instruments, and the animal; anesthetics and post-operative analgesics, their dosages and route of administration, etc. If an increase in animal numbers greater than 10\% of the original number approved is requested, the PI must provide the reasons for the need of additional animals and justification for the number requested. Reviews of significant amendments by the IACUC do not differ from reviews of full protocols.
Alternatives to Painful Procedures: Overview

The regulations of the Animal Welfare Act (AWA) require that the principal investigator consider alternatives to procedures that may cause more than momentary or slight pain or distress to animals. These may include, but are not limited to such procedures as surgery (even under anesthesia), prolonged restraint, food deprivation, and chemical immobilization of a conscious animal. If a protocol includes such activities, the investigator is required to demonstrate that no alternatives exist, or that existing alternatives are inadequate for that protocol. The meaning of alternatives, in this case, includes not only looking for a different, less stressful procedure (refinement), but also looking into using other, lower order species or non-animal models (replacement), and (not or!) using fewer animals (reduction).

PIs must provide a written narrative of the sources consulted to determine whether or not alternatives exist to procedures that cause pain or distress. The USDA, which is charged with enforcing the AWA, has promulgated two policies that assist investigators in understanding how to comply with this regulation. The first policy provides the definition of what is considered a painful or distressful procedure, and provides examples of both. In general, any procedure that would be expected to cause more than slight or momentary and and/or distress in a human to which the procedure is applied is considered to be painful and/or distressful in animals. The other policy provides guidance in what the minimal written narrative should include. In general, this requires a narrative describing a specific literature search for alternatives, including databases searched, key words used, and the date of the search. If alternatives are described but will not be used, the principal investigator must describe why these are not adequate for the project described.

Guidelines for Searches to Alternatives for Animal Use

Introduction

The Animal Welfare Act Regulations, Section 2.31 and USDA require that a written narrative be provided by the Principle Investigator (PI) to determine whether or not alternatives exist to procedures that may cause pain or distress in animals used for teaching or research. In addition, if alternatives exist but are not used, the PI must justify why this is the case. Although searching for animal alternatives may seem to be an overwhelming task, it is hoped that the information in this document will assist animal users with this federally mandated task.

Definition of Alternatives

Alternatives refer to methods or approaches which result in refinement of procedures which lessen pain and/or distress; reduction in numbers of animals required; or replacement of animals with non-whole-animal systems or replacement of one animal species with another, particularly if the substituted species is non-mammalian or invertebrate.

Animal Welfare Act Regulations

The AWA regulations require the Institutional Animal Care and Use Committee (IACUC) to determine that "the principle investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources used to determine that alternatives were not available." The PI must provide scientific justification to

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the IACUC if alternatives are available but not used.

Types of Studies Requiring an Alternatives Search

Not all animal use protocols require an alternatives search. Only studies utilizing procedures which result in more than momentary or slight pain or distress require a search. Examples include: toxicity and infectious diseases research, tumor induction or transplantation studies, survival and non-survival surgical procedures, pain research, in vivo monoclonal or polyclonal antibody production procedures, fluid and/or food restriction, and prolonged restraint. This list is not exhaustive. If you are unsure whether a search is required, please consult the IACUC office or the Laboratory Animal Resources (LAR) veterinary staff.

Alternatives Narrative: The written narrative for the search for alternatives must include the following minimum: methods of searching, databases searched, the date of the search and years covered, and key words and/or search strategy used. If alternatives exist to the proposed animal procedures in the protocol, the investigator must scientifically justify why these alternatives are not used. This information must be updated with each three-year renewal of the animal use protocol. DO NOT simply provide a bibliography! It is the investigator’s responsibility to review the literature and summarize the findings.

Database and Web Site Searching: Computerized storage of scientific information makes database searching relatively easy. Databases frequently used, and available on line for IUB: for alternatives searches include TOXLINE, GRATEFUL MED, Cancerlit, Bioethics, and AIDSLINE (National Library of Medicine), and CAB Abstracts and AGRICOLA. Depending on the subject, searching several of these databases for alternatives is considered adequate by the IACUC.

Problems often arise in choosing keywords and search strategies that will yield the most pertinent information. Appropriate search terms or keywords include animal testing alternatives, alternatives, tissue culture, cell culture, simulation, in vitro, and model. Additional keywords can be found on the UC Center for Animal Alternatives web page (see below). These terms are useful, but are not the only terminology possible. The following websites provide additional information investigators may find helpful in completing an alternatives search:

The regulations of the Animal Welfare Act (AWA) require that the principal investigator consider alternatives to procedures that may cause more than momentary or slight pain or distress to animals. PI's must provide a written narrative of the sources consulted to determine whether or not alternatives exist to procedures which cause pain or distress. The USDA, which is charged with enforcing the AWA, has promulgated two policies that assist investigators in understanding how to comply with these regulations. The first policy provides the definition of what is considered a painful or distressful procedure, and provides examples of both. In general, any procedure that would be expected to cause more than slight or momentary and and/or distress in a human to which the procedure is applied is considered to be painful and/or distressful in animals. The second policy provides guidance in what the minimal written narrative should include. In general, this requires a narrative describing a specific literature search for alternatives, including databases searched, key words used, and the date of the search. If alternatives are described but will not be used, the principal investigator must describe why these are not adequate for the project described.

Searchable Databases and Web Resources:

- Animal Welfare Information Center (AWIC)

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• John Hopkins Center for Alternatives to Animal Testing - CAAT
  o http://altweb.jhsph.edu/
• NORINA Alternatives Databases
  o http://oslovet.veths.no/fag.aspx?fag=57
• UC Center for Animal Alternatives
  o http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm
• Monoclonal Antibody Production: A Report of the Committee on Methods of Producing Monoclonal Antibodies, ILAR, National Research Council
• AWIC Informational Resources for Adjuvants and Antibody Production
  o http://www.nal.usda.gov/awic/pubs/antibody
• Monoclonal Antibody Production: The Report and Recommendations of the ECVAM
• Antibody Resource Page
  o http://www.antibodyresource.com/
Section 10

The IUB Occupational Health and Safety Program for Personnel Involved in Animal Care and Use

Federal regulations mandate that the animal care and use program include an occupational health and safety program that includes:

* Hazard identification and risk assessment

* Personnel training

* A program of personal hygiene

* Facilities, procedures and monitoring which support occupational health and safety

* Safeguards for animal experimentation involving hazards such as carcinogens, biohazardous agents, and anesthetic gases.

* Medical evaluation and preventive medicine for personnel

The Occupational Health Program for IUB can be found: [http://www.indiana.edu/~lar/ohs/](http://www.indiana.edu/~lar/ohs/)
Section 11

Procurement, Transfer, and Transport of Laboratory Animals

Specific policies apply for procurement of all vertebrate animals to be used for teaching, testing or research.

The following policies apply to procurement of animals to be used for teaching or research.

- Laboratory animals may not be obtained prior to approval of an animal use protocol that describes the intended use of that animal.
- LAR must be notified in advance of procurements of animals from off-campus sources.
- The LAR office will approve procurements based on vendor, number and type of animals requested, and protocol approval.
- Animal orders should be placed by the appropriate staff member after receipt of approved requisition documentation.
- Laboratory animal production, e.g., in breeding programs, must be covered under an approved protocol.
- Investigators may, in some cases, desire to transfer animals between approved animal protocols, between campus animal care units or ship animals off campus to another investigator. Transfers of animals between approved protocols are treated as an animal procurement and must comply with the procedures detailed above.
- Investigators who wish to transport or ship animals off campus must contact LAR first to make arrangements.
- Health reports and/or certificates may need to be provided prior to the shipment of animals to another institution.
- All animal transport must be done in accordance with Animal Welfare Act regulations and with consideration for the animal's health and well being.
Section 12

Evaluating Pain and Distress in Research and Teaching Animals

Animals must be observed at least daily by animal care personnel or by research personnel. In all cases, observations should include checking for signs of pain or distress. Unanticipated pain or distress (e.g., due to illness or injury not described in an approved animal use protocol) must be reported to the LAR veterinary staff.

According to federal regulations, the researcher is responsible for consulting with the attending veterinarian or designee in the planning of procedures that may cause more than momentary or slight pain or distress in animals. At IUB, this is built into the protocol review process in that each protocol is reviewed by one of the LAR veterinarians. Pain and distress that are anticipated in the course of an experimental manipulation, surgical procedure, teaching, or testing exercise must be described in an animal use protocol. Drugs for alleviating pain must be provided unless approval for withholding such agents has been granted via an animal use protocol.

Animals may exhibit pain and distress in ways not obvious to the casual observer. Research personnel should report immediately any unusual behavior in research animals to animal care personnel or the LAR.
Section 13

Veterinary Care: Reporting Sick, Injured or Dead Animals

All unanticipated illness, injury and deaths of animals housed in an IUB animal facility should be reported immediately to LAR. Whoever identifies the medical concerns, animal care staff or research personnel, must ensure that the LAR veterinary staff is notified in a quick and reliable manner.

With respect to animals that are expected to become sick or die as a result of the experimental procedures, animal illnesses and deaths must be reported.

With the exception of first-aid or emergency life-support provided by appropriately trained personnel, animals should not be treated for illness or injury prior to consultation with an LAR veterinarian. Animals found dead should not be discarded or frozen prior to consultation with LAR.
Section 14

Animal Health Maintenance, Surveillance and Quarantine

Animals that are suspected of carrying pathogenic organisms will be evaluated by a LAR Veterinarian.

When incoming animals or those in established colonies are determined to be carrying disease that could endanger other animals or research programs, the veterinarians may recommend that they be placed under quarantine or euthanized.

Investigators should consult with LAR prior to arranging to acquire animals from a non-approved vendor or non-commercial source such as another university or research institution.
Section 15

Reporting of Animal Welfare Concerns and/or Animal Care and Treatment Deficiencies

Any concern about the welfare of animals on the IUB campus can be confidentially reported to the Office of the Vice Provost for Research (855-3931) the Attending Veterinarian (855-1400), or any IACUC member. Concerns will be brought to the IACUC chair, who will appoint appropriate IACUC members to investigate. The IACUC will report the findings and recommendations to the Institutional Official.