



*Institutional Animal Care and Use Committee  
Updated June, 2008*

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**COMMON ERRORS THAT CAN RESULT IN  
PROTOCOL APPROVAL DELAYS.**

It is the aim of the IACUC and the administrative staff to review protocols in a timely manner. Listed below are common reasons that can delay approval of a protocol by the IACUC. Attention to details and elimination of simple housekeeping errors will expedite the process and reduce unnecessary delays in the approval process.

**1. Use the Current Forms.**

All protocols submitted for IACUC review must be prepared using the most current protocol forms. Obtain the updated version of the relevant [IACUC forms](#) from our website before starting to write. Submission of a protocol prepared using an out-of-date form will result in the form being returned without review.

**2. Sign the Animal Protocol Form.**

The PI must submit a one *signed hard copy* of the finalized Animal Use Protocol form to the IACUC coordinator, along with an electronic version that contains all of the changes that were generated by the reviews before an approval letter will be generated.

**3. Be Sure All Personnel Listed on the Protocol Have Completed the Required Training.** This includes the relevant on-line module(s) as well as any specialized training necessary to enable them to perform their duties involving animals. The [Training Requirements](#) are elaborated on the IACUC web site. Note that *all PIs* must complete specific on-line training modules as well! If all personnel have not yet completed the requirements, indicate a plan for completion before submitting the protocol; a final letter will not be issued until the requirements are met.

**4. Provide a Synopsis/Abstract in Layman's Language.**

On the first page of the Animal Utilization Application Form, the PI is asked to provide a description of the proposed work that involves vertebrate animals *using language that a non-scientist could understand*. In other words, a high school student should be able to understand this portion of the protocol application. Scientific jargon should be avoided. Cutting and pasting the abstract from your grant proposal is not acceptable since that typically contains too much scientific jargon and requires considerable knowledge of the subject being discussed. IACUCs are mandated by law to include a non-scientist member, as well as a member who is not affiliated with the University. Since everyone on the Committee should be able to clearly understand the intent and significance of the study, the IACUC will insist that this section of the protocol is appropriately written.

**5. Be Sure to List the Correct Animal Numbers and Justify Proposed Use.**



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A common error is that the number of animals requested does not match up with the number of experiments that have been outlined. Another common error is that “an approximate number” of animals is requested (e.g. ~100-200 mice) without justifying the numbers by specific experimental design and statistical requirements of the scientific study. If there are large numbers, or numerous and different strains of animals or multiple experiments, consider including a table that outlines the experiments and the number of animals needed. Finally, be sure that the total number of animals indicated in section IV.A. of the Animal Use protocol matches the total number of animals that are classified by different pain/distress categories in section IV.D.3. Provide compelling justification for your animal numbers.

### **6. Use the IACUC Guidelines**

There are presently a significant number of [Guidelines](#) that have been approved by the IACUC and that are posted on our web site. The Guidelines describe standard procedures that should be used by the principal investigator in preparing the protocol. Stating that you will follow the IACUC guidelines for a given procedure is appropriate. If you propose to deviate from any of the approved Guidelines, you must justify the change on scientific grounds in the protocol.

### **7. Discuss Drug / Treatment Effects.**

When drugs or experimental agents are administered to conscious animals, the principal investigator should indicate overt actions of the drug/agent, whether side effects are anticipated, how potential adverse actions will be monitored and what actions will be taken to ensure the animal's well being. If the effects of the drug/agent/treatment are unknown, the protocol should indicate they might impact on behavior or animal health and discuss how this will be monitored, including actions that will be taken if adverse effects occur. In many cases, a comprehensive post-procedural monitoring plan may be required. Ignoring the potential for adverse effects will not go unnoticed and will result in delays until appropriate revisions are made.

### **8. Use the Correct Pain/Distress Categories for your Experiments.**

It is the USDA position that terminal surgery has the potential for pain. Thus, the law requires that the investigator consider *alternatives* to the procedure (see #10 below) and that the IACUC review and approve the procedure. Accordingly, protocols involving terminal surgery procedures will be classified as **Category D**. For additional information on pain/distress categorization of animals, see the specific [Guidelines on Assigning Pain/Distress Categories](#) that are relevant to this issue on the website.

### **9. Do a Thorough and Appropriate Search for Alternatives - If Required.**

If your studies include ANY animals in Category D or E, you must complete the Alternatives section of the Animal Protocol form. More information about the “Three R’s” (Replacement, Reduction and Refinement) can be found on the IACUC website



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under [Alternatives Search Information](#) as well as pages 1-3 of the [Handout on Basic Issues in Animal Research](#). Each of the Three R's must be addressed in the narrative.

### **10. Anesthesia and Analgesia**

- If a research, testing or teaching procedure is likely to cause pain and discomfort that would be reduced by the administration of anesthesia, the animal shall first be rendered incapable of perceiving pain and be maintained in that condition until the procedure is completed.
- The person responsible for direct supervision or implementation of anesthesia shall be qualified by training and experience to assess the animal as an anesthetic risk, and shall monitor the phases and depth (plane) of anesthesia and determine the recovery status for discharge.
- All personnel who are performing anesthesia must be technically qualified in procedures for induction, maintenance and postoperative care of the species that is being used. The agent used must be appropriate for both the species being utilized and the requirements of the experimental procedure. See [Guidelines on Anesthesia](#) for additional information.
- Post-procedural care of animals shall include the use of analgesics as required to minimize discomfort and the consequences of any disability resulting from the experiment or teaching procedure, in accordance with acceptable practices in veterinary medicine. Post-operative or post-procedure care and the duration of such care must be outlined in the protocol. See [Guidelines on Analgesia](#) and [Guidelines on Post -procedure Monitoring](#) for more information. If the PI proposes to deviate from the Guidelines, appropriate veterinary consultation should be made and scientific justification provided in the protocol

### **11. Surgery**

Any surgical procedures should be completely explained in the protocol. The PI must ensure and state that: a) For USDA covered species, a facility dedicated for aseptic surgery shall be used. b) For rodents or lower animals, the survival surgery will be performed using sterile instruments, surgical gloves, and aseptic procedures (see [Guidelines for Aseptic Surgery on Rodents](#)). All surgeries must be performed and/or directly supervised by persons qualified by training and experience. Post-surgical care, analgesia and animal monitoring shall be provided by qualified personnel and discussed in protocol (See #11 above for links)

### **12. Define Humane Endpoints for the Experimental Animals.**

The PI must articulate the potential adverse effects of experimental procedures on animals, present an appropriate monitoring plan, and have defined humane endpoints that will dictate when an animal is removed from a study early and is euthanized. *A Humane Endpoint is NOT the same as an experimental endpoint!* Thus, naive, inappropriate



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statements in a submitted protocol such as “the humane endpoints to be used are the sacrifice of animals at one and at two weeks after treatment with agent X” are unacceptable and will require revision. The IACUC will be most particular about this important issue when there is potential for experiments to cause pain and distress, but all protocols should include information about which clinical signs will trigger the decision for euthanizing an animal to prevent unnecessary pain and distress. See [Guidelines for Humane Endpoints](#) for additional information.

**13. Euthanizing Animals.**

Only methods that are approved by the American Veterinary Medical Association Panel on Euthanasia should be used. All personnel who are performing euthanasia must be qualified by training and experience in the euthanasia methods. See IACUC [Guidelines for Euthanasia](#) as well as the specific [Guidelines for the Use of CO<sub>2</sub> for Euthanasia](#). For neonates, see [Guidelines for Euthanasia of Neonatal Rodents](#).

The BRF clinical staff has the ethical and legal obligation to euthanize animals that are in pain and/or distress exceeding that described in the approved IACUC protocol. The normal procedure is to first attempt contacting the PI or designate prior to euthanizing the animal. However, if the attempt is unsuccessful, humane considerations will prevail and the veterinarian, by law, has final authority over animal welfare at the university. Investigators concerned about rare, highly valuable animals (e.g. transgenic animal that required many years to develop) should draw up special action / emergency plans with the BRF staff.

**14. Biohazards, SOPs and other Safety Documents - Get Necessary Pre-Approvals.**

If the protocol involves the use of biohazards or isotopes in animals, the principal investigator must obtain and submit signed copies of relevant safety approvals from the [Office of Environmental Health and Safety](#). In most cases, the PI will need to provide signature copies of Standard Operating Procedures and may need to file a Special Animal Safety Protocol (see [Instructions to Principal Investigators](#)). Final approval of your animal protocol will NOT be granted without signature copies of any necessary safety documents that the IACUC feels are needed for your particular project!