COMMON ERRORS THAT CAN RESULT IN DELAYS IN ANIMAL PROTOCOL APPROVAL

It is the aim of the IACUC to review protocols in a timely manner. This document discusses avoidable issues that can result in delays in the review and approval of an IACUC protocol. In all cases, attention to important details can expedite the review process and reduce unnecessary delays in approval.

1. Use of out-of-date application forms

Protocols submitted for IACUC review must be prepared using the most current protocol forms obtained from the IACUC website. Submission of a protocol prepared using an out-of-date form will result in the application being returned without review.

2. Failure to submit all required materials electronically to IACUC@rosalindfranklin.edu

The following attachments are required:

- The completed protocol as a **WORD** file*
- Breeding appendix (if applicable) as a **WORD** file*
- The IRSR form-signed by PI as well as EHS (**pdf**)
- Grant related materials if federal funding is involved (**pdfs**)
- New SOPs not currently on file for your lab (**pdfs**)

*(*Do not submit pdfs of protocol or the breeding appendix).*

3. Not following instructions for preparing a "non-technical summary"

PI must provide a description of the proposed work involving vertebrate animals *in language that a non-scientist could understand* in this section of the application. Scientific jargon should be avoided. Cutting -and -pasting the abstract from a grant proposal is not acceptable since that typically contains excessive technical language that requires considerable knowledge of the subject being discussed. IACUC is mandated by law to include a non-scientist member, as well as a community member who not affiliated with the University (often a nonscientist). Since *everyon*e on the Committee should be able to clearly understand the intent and significance of the study as it involves animals, the IACUC will insist that this section of the protocol is appropriately written. We suggest targeting the language in this section so it easily understood by an average 7th grade student.

4. Inconsistent animal numbers and/or inadequate justification

A common error is that "an approximate number" of animals is requested (e.g. ~200-400 mice) without justifying the numbers by reference to experimental design or statistical requirements of the study. A power analysis is always preferred. If there are large numbers, numerous different strains of animals, and/or multiple experiments, including a Table that outlines the experiments and the number of animals needed will be useful. Those can be cut/pasted into the protocol application. Finally, ensure that the total number of animals indicated in section IV.A. of the protocol matches the total number of animals that are classified by different pain/distress categories in section IV.D.3 of the protocol and that you have included breeders if relevant.

5. Insufficient documentation of personnel training
Training includes the relevant on-line CITI module(s) as well as hands-on specialized training necessary to enable them to perform their duties involving animals. This should be discussed in the application. If all personnel have not yet completed specialized training requirements that appear necessary for the study, check the "in progress" box and describe the plan for their completion before they can work independently. That plan should include notification to the IACUC when specialized training is completed.

6. Not following the available IACUC guidelines
There are a significant number of guidelines that have been approved by the IACUC and posted on our web site. The guidelines describe standard procedures as well as drug formularies that should be used. If you propose to deviate from any of the approved IACUC guidelines, you must justify the change on scientific grounds in the protocol.

7. Failure to discuss adequately discuss drug / treatment effects.
When drugs or experimental agents are administered to conscious animals, the protocol should indicate expected actions of the drug/agent, side effects that are anticipated, and a discussion of the monitoring plan for possible adverse effects, along with the actions that will be taken to ensure the animal's well-being. If the effects of the drug/agent/treatment are completely unknown, the protocol should discuss how this will be monitored, including actions that will be taken if adverse effects occur. In such cases, a pilot study on a small number of animals along with a comprehensive post-procedural monitoring plan is prudent and should be proposed. Ignoring the potential for adverse effects will not go unnoticed in review and will result in delays until appropriate revisions are made.

8. Failing to use the proper Pain/Distress categories for your experiments
Many procedures, including all surgeries, have the potential for pain. Always use the highest level to categorize experimental animals based on the potential for pain/distress. For additional information see the Guidelines on Assigning Pain/Distress Categories on the IACUC website.

9. Not providing a thorough description of how Alternatives were considered
If your studies include any animals in Category D or E, you must complete the Alternatives section of the protocol application, including a narrative that addresses each of the "3 R's" (Replacement, Reduction and Refinement). More information about the "3 R's" can be found on the IACUC website.

10. Not providing adequate description of anesthesia or analgesia use

- 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 must 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, monitor the phases and depth (plane) of anesthesia as well as determine when recovery is complete enough for returning the animal to its housing area.
- All personnel who are performing anesthesia must be technically qualified in the 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.
- Post-procedural care of animals must 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. If the PI proposes to deviate from the IACUC guidelines, appropriate veterinary consultation should be made and scientific justification provided in the protocol .

11. Incomplete descriptions of surgical procedures

Any surgical procedures to be performed should be completely explained in the protocol. The protocol must clearly state that:

a) For USDA covered species, a facility dedicated for aseptic surgery in the BRF and aseptic procedures will be used.
b) For rodents or lower species, the survival surgery does not require a dedicated area but will be performed using sterile instruments, surgical gloves, and aseptic procedures.
c) Surgeries must be performed or directly supervised only by persons qualified by training and experience. Post-surgical care, analgesia and animal monitoring shall be provided by qualified personnel and discussed in detail in the protocol.

12. Failure to define Humane Endpoints for experimental animals.

The protocol must state 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 early from a study (and/or be euthanized) to prevent unnecessary pain and distress. *A Humane Endpoint is NOT the same as an experimental endpoint!* Thus, naïve and inappropriate statements in a submitted protocol such as "the humane endpoints to be used are the euthanasia of animals 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. Inadequate information about euthanasia

Only methods that are approved and listed in the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition (or subsequent edition) should be used. All personnel who are performing euthanasia must be qualified by training and experience in the euthanasia methods. The guidelines on the IACUC website should be followed and deviations justified in the protocol.

The veterinary 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. When animals that appear to be in pain/distress are found by the BRF staff or veterinarians, 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 veterinarian and BRF staff.

14. Failure to submit approved safety documents in a timely manner

If the protocol involves the use of biohazards, chemical hazards, lasers, radioisotopes or radiation in animals, the PI 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 (SOP) for working with such materials. Final approval of an animal protocol will NOT be granted without signature copies of all necessary safety documents that the IACUC feels are needed for your particular project!