



*Institutional Animal Care and Use Committee*  
*February 2008*

**GENERAL INFORMATION ON PROTOCOL SUBMISSION PROCEDURES**

Based upon Federal Regulations all research, teaching and/or testing on live vertebrate animals, regardless of the funding source, requires approval of an Animal Use Protocol (AUP) by the Institutional Animal Care and Use Committee (IACUC) prior to implementation.

Other levels of review and approval may also be required if the project involves the use of hazardous agents in animals (e.g. Environmental Health and Safety, Radiation Safety). Final IACUC approval of the Animal Use Protocol will only be granted after all safety approvals have been obtained.

**Who can submit an Animal Use Protocol as Principal Investigator?**

The following individuals can be the signatory Principal Investigator (PI) on an Animal Use Protocol at Rosalind Franklin University:

- Full ranked academic faculty: Professor, Associate Professor, Assistant Professor or Instructor
- Prefixed academic rank faculty: Research-, Clinical-, Adjunct- or Visiting- professor series appointed for 50% (or more) time at the university.

Postdoctoral fellows, research associates, students and staff may assist in preparation of an Animal Use Protocol but cannot be the signatory Principal Investigator. In cases where outside grant funds are involved, a faculty sponsor must be identified to serve as the overseeing PI on the Animal Use Protocol.

**What is the timetable for Animal Use Protocol submission?**

The Institutional Animal Care and Use Committee (IACUC) typically meets on the third Wednesday of every month. The completed Animal Use Protocol application (as well as Annual Renewal applications and Significant Change applications) must be received by the IACUC Office no later than 3 weeks prior to the next scheduled meeting in order to be considered in the next IACUC cycle. The deadlines are designed to ensure that all protocols can be comprehensively reviewed in a timely manner.

**What needs to be submitted?**

Complete and submit an electronic copy and one signed hard copy of the Animal Use Protocol application to the IACUC Coordinator: (deb.holderbaum@rosalindfranklin.edu; campus mail: IACUC/BRF Office).



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- Always use the most current version of the application form (downloaded from the IACUC web-site: <http://www.rosalindfranklin.edu/animal/forms.htm>).
- If the project is supported by (or is being submitted to) a federal granting agency you must also submit the cover page, abstract and vertebrate animal sections of the federal grant application associated with the animal protocol.
- If safety approvals are required (e.g. radiation, hazardous agent use in live animals) submit the approval letters/documentation from the relevant safety office. Approval for hazardous material use in animals can be sought in parallel with the Animal Use Protocol review, but final IACUC approval will not be granted until all safety approvals are received in the IACUC office.

### **How long is IACUC approval valid?**

IACUC approves animal protocols for a three-year period - but **this is contingent upon the filing and approval of annual renewal applications by the PI**. Only two annual renewals are allowed and then a full new Animal Use Protocol application is again required. This is the case no matter how long a grant funding period may be (e.g. NIH may fund a grant for 5 years but IACUC requires a full new protocol application every 3 years and annual renewal applications in the interim periods).

The PI should keep track of the annual expiration dates for their protocols. To assist with this task, the IACUC office notifies the PI that an Annual Renewal application form is due 2-3 months prior to a protocol's annual date of expiration. The annual renewal form must be completed and submitted to the IACUC in a timely manner for review. Failure to submit a renewal application will result protocol expiration. Under federal regulations, no work with animals can be done under an expired protocol and such activity will be considered serious non-compliance.

The IACUC coordinator will also notify the PI when a protocol is due for its "triennial renewal" – which is basically the time at which a full new Animal Use Protocol application is needed. This reminder will be sent 3-4 months in advance of the final expiration of the protocol. PIs should always allow ample time for protocol preparation and review.

### **What about modifications to a previously approved Animal Use Protocol?**

Major changes/amendments to approved protocols necessitate the submission of a Significant Change to an Approved Animal Use Protocol application to the IACUC and must be approved before the changes can be implemented by the investigator. Always use the latest application form for significant changes that can be downloaded from the IACUC website (<http://www.rosalindfranklin.edu/animal/forms.htm>).



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Examples of the types of changes that would necessitate submission of a Significant Change application include: Switch from non-survival to survival surgery, change in the degree of invasiveness of a procedure or discomfort to an animal, change in species, change in study objectives, increase in the number of animals >20% of the original number approved, change in anesthetic agent(s), the use or withholding of analgesics, or methods of euthanasia, change in the duration, frequency, or number of procedures performed on an animal, or a change in PI. Significant Change applications are reviewed by the IACUC in a manner identical to new Animal Use Protocols. The IACUC can require the PI to submit a new Animal Use Protocol for review if it considers the number or types of changes to be excessive.

Minor changes to a protocol can be addressed in several ways: A letter to the IACUC Chair or through the filing an Administrative Change form (use the latter only if the change is funding source, title of project or room location (download this form from: <http://www.rosalindfranklin.edu/animal/forms.htm>). Other types of minor changes are personnel addition/deletion (except for PI), increase in number of animals needed that is <20% of that originally approved), change in genetic background or strain within a species, change in treatment that involve small adjustments in timing, dose, route of administration (only if this does NOT alter the degree of invasiveness or specific objectives). The requests will be administratively reviewed and can be approved by the IACUC Chair. If the Chair views the proposed change as significant rather than minor, the PI will be instructed to file a Significant Change application.

**What about congruency requirements for federal grants and animal protocols?**

The University must assure the federal government that all of the animal work described in a grant is covered under an approved Animal Use Protocol. Thus, PIs must submit a copy of the Title Page, Abstract and Vertebrate Animal Section of any federal grant funding the work described in the protocol. The IACUC will do a comparison of the relevant sections of the grant with the Animal Use Protocol to verify congruency as part of the review process. In some cases, it may be necessary for the PI to submit a Significant Change application if the IACUC feels that congruency is not adequate.

**“Expedited” Reviews**

“Expedited” reviews necessitate a full committee review (and usually a special session of the convened IACUC). This will only be done in unusual circumstances at the discretion of the IACUC Chair (and there is of course no guarantee that approval will be granted). The IACUC will not do “expedited” reviews simply because the PI failed to submit a protocol and protocol associated documents in a timely manner.