



## **GENERAL INFORMATION ON ANIMAL PROTOCOL SUBMISSION**

Federal Regulations state that all research, teaching or testing on live vertebrate animals, regardless of the funding source, requires prior approval of an animal protocol by the 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. by Environmental Health and Safety, Radiation Safety, etc.). Final IACUC approval of the animal protocol will only be granted after all safety approvals have been obtained.

### **Who can submit an animal protocol as Principal Investigator?**

The following individuals can be the signatory Principal Investigator (PI) on an animal 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 protocol but cannot be the PI. In cases where outside grant funds are involved, a faculty sponsor must be identified to serve as the overseeing PI on the animal protocol.

### **What is the timetable for animal protocol submission?**

Protocols are accepted on a continuous basis with the following caveat:

While most protocols will be reviewed by the Designated Review process, some protocols could may be referred to Full Committee Review. In that case, a 3-week window before the next scheduled IACUC meeting is needed for a protocol to be placed on the agenda for the next meeting (or it will automatically be placed on the following month's agenda). The IACUC meets on the third Wednesday of every month.

### **What needs to be submitted?**

An electronic copy of the following should be sent to: *IACUC@rosalindfranklin.edu*.

- A completed current protocol application form (downloaded from the IACUC web-site) as a WORD document.
- If breeding is involved, a completed current breeding application form (downloaded from the IACUC web-site) as a WORD document.
- If the project is supported by (or is being submitted to) a federal granting agency you must also submit copies of the abstract and the vertebrate animal section of the grant application.
- If safety approvals are required (e.g. radiation, hazardous agent use in live animals) submit pdfs of signed approval letters/documentation from the relevant safety office. *Note that approval for hazardous material use in animals can be sought in parallel with the animal protocol review, but final IACUC approval will not be granted until all safety approvals are received in the IACUC office.*

- The Institutional Research Safety Report Form (IRSR) that is signed by the RFUMS Environmental Health and Safety Department

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

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

The PI should keep track of the annual expiration dates for his/her protocols. The addition, the IACUC office will notify the PI two months prior to a protocol's annual expiration date that an Annual Renewal application form is due. 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. Continuing to work without an approved protocol will be considered an act of serious non-compliance.

The IACUC office will also notify the PI when a protocol is due for its "triennial renewal" – which is basically the time at which a complete new animal 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 the review.

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

Major changes/amendments to approved protocols always require the submission of an Application for Significant Change to Animal Protocol to the IACUC that must be reviewed and approved by the IACUC before the changes can be implemented by the investigator.

1. Examples of the types of changes that would necessitate the submission of a Significant Change application include proposed changes:
  - in study objectives;
  - from nonsurvival to survival surgery;
  - resulting in greater pain, distress, or degree of invasiveness;
  - in species, strain, or any number of animals used (increase of even one animal above the approved number is considered significant);
  - in Principal Investigator (PI);
  - in drugs used for anesthesia, analgesia, sedation;
  - in euthanasia method
  - in duration, frequency, type, or number of procedures performed on an animal.

Other changes may be considered significant as determined on a case-by case basis by the IACUC. Significant change applications are reviewed by the IACUC in the same manner as new animal protocol applications. The IACUC can require the PI to submit a separate new animal protocol for review if it considers the number or types of significant changes to

be excessive. A good rule of thumb is – if you are checking more than 3 boxes on the cover page of the Significant Change application form, you may be asked to submit a new protocol. Please consult the IACUC Chair if you have questions about this issue!

2. Examples of **minor changes** to a protocol would include:

- personnel additions/deletions (except for the PI),
- changes in treatment that involve minor adjustments in timing, dose, route of administration of agents (*except drugs used for anesthesia or analgesia*).

There is no special form for minor protocol changes, they should be communicated in advance by submitting a detailed letter to the IACUC that discusses the proposed changes. These requests will be administratively reviewed by the IACUC Chair. If the Chair views the proposed change/s 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 Federal grant is covered under an approved animal protocol. Thus, PIs must submit a copy of the Abstract and Vertebrate Animal Section of any Federal grant funding the work described in the protocol. The IACUC reviewer/s will do a comparison of the relevant sections of the grant with the animal 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 typically necessitate a Full Committee review (and are usually done at 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 an animal protocol in a timely manner. A good rule of thumb is that a PI in good standing with the IACUC may be granted one expedited review per lifetime. PLEASE PLAN AHEAD!