

HOW DO I....?

...submit an application for a new protocol?

Use the David H Murdock Research Institute Institutional Animal Care and Use Committee protocol submission form that can be found at: <http://dhmri.org/services-support/ncrc-members-portal>. Plan to submit your protocol before the second Monday of the month in order to be ready for the next regularly scheduled IACUC Meeting held on the first Wednesday of the month. Should you miss the intended submission deadline your protocol submission, a review will occur at the next month's IACUC meeting.

Submit the protocol and all associated appendixes to iacuc@dhmri.org for pre-review.

- The pre-review checks the protocol for completeness and compliance with information requirements as indicated in the PHS Policy and Animal Welfare Act.
- Based on pre-review the protocol may be returned for editing by the investigator, and resubmitted prior to distribution.

Consult with the Attending Veterinarian about standard SOPs such as anesthesia, euthanasia, etc. Submit draft protocol to the IACUC Coordinator to obtain the Attending Veterinarian's review. Revise, carefully addressing Attending Veterinarian's comments.

Return the revised protocol to the IACUC Coordinator. The IACUC Coordinator will distribute the protocol to the IACUC members. The IACUC members will determine if it can be reviewed by Designated Member Review (DMR) or if it requires Full Committee Review (FCR). You will be notified of the Committee's decision.

If any Committee member objects to DMR, the protocol must go to Full Committee Review. In either case, a primary reviewer is assigned.

If your protocol is reviewed via DMR, you will be notified of the reviewer's comments and asked to submit a revised protocol to the IACUC Coordinator. If then approved, you will be notified.

If Full Committee Review is requested, the protocol will be discussed by the Full Committee at the next DHMRI IACUC Meeting, and voted upon. **If approved**, you will be notified by the end of the next business day by the IACUC Coordinator. If the protocol requires modification, you will be notified of the IACUC's request for changes by the end of the next business day.

Some protocols may be approved with the need for minor technical modifications.

The AV and primary reviewer will work with the Principal Investigator to modify unapproved protocols so they may be approved.

Work may commence as soon as the protocol is approved, but not before.

Following approval the Principal Investigator will receive a signed copy of the protocol for his/her records.

Because of varying decisions along the way, protocols may be approved very quickly, or if many revisions are needed, not so quickly. The time from submission to approval depends primarily on how carefully it is written, and how quickly revisions are made.

...re-submit a returned protocol?

Email it to the IACUC at iacuc@dhmri.org after revision.

...respond to IACUC comments?

The investigator is informed of the modifications needed and returns a response to iacuc@dhmri.org. The response is sent to the reviewer to determine if the investigator's response is acceptable or if further detail is necessary.

If the response is acceptable to all designated reviewers, the IACUC Chair issues an approval letter.

If further detail is necessary, the investigator is notified and returns a response. If the response is acceptable to all reviewers, the IACUC Chair issues an approval letter that is sent to you by e-mail.

If a principal investigator disagrees with the revisions required by the IACUC to obtain approval of a protocol, or with the disapproval of a protocol, the investigator may, with the concurrence of the appropriate Dean/Department Head or Chair, submit a written appeal to the IACUC stating the reasons for objecting to the required changes and/or proposing an alternative resolution. The Principal Investigator may also request a meeting with the IACUC to discuss the differences of opinion and resolve them. If no satisfactory resolution is reached, the principal investigator may submit a written appeal to the Institutional Official requesting assistance. The Institutional Official will attempt to mediate a solution to the situation. However, neither the Institutional Official nor any other administrative official can override a decision by the IACUC.

...submit a One Year or Two Year Renewal of an approved protocol?

Use the David H Murdock Research Institute IACUC Protocol Continuation or Cancellation form found at: <http://dhmri.org/services-support/ncrc-members-portal>

The Protocol Continuation Form should be submitted to the IACUC at iacuc@dhmri.org at least 30 days before the anniversary of the approval. Continuations without modification (which includes already approved amendments) will be reviewed and approved by the Chair of the IACUC. Continuations that request modifications will be handled along with the requested amendment. See "How do I amend my approved protocol?" below.

...submit a Year Three Renewal of an approved protocol?

Protocols expire at the end of the three year period, and a new protocol must be submitted to the IACUC. Use the David H Murdock Research Institute IACUC new protocol submission form found at: <http://dhmri.org/services-support/ncrc-members-portal>

The Three Year Renewal is actually a *de novo* protocol application, and handled as a new protocol application (see above).

...amend my approved protocol?

Use the DHMRI IACUC Protocol Amendment Form found at: <http://dhmri.org/services-support/ncrcmembers-portal>

As with new protocol submissions, consultation with the Attending Veterinarian must occur on all protocol amendments prior to review by the IACUC. The veterinarian will review the protocol amendment form and provide written comments so that revisions to the form, if suggested, can be made prior to IACUC review.

Any changes in ongoing active protocols must be submitted to the IACUC using the **Protocol Amendment Form**. The IACUC Coordinator, in coordination with the IACUC Chair and/or Attending Veterinarian, will make a determination if the changes are considered significant or minor using the following criteria which was compiled by the NIH Office of Laboratory Animal Welfare as examples of significant changes (*this is not an exhaustive list*):

- a. Changes in the objectives of the study;
- b. Proposal to switch from non-survival to survival surgery;
- c. Changes in species or an increase in the number of animals of greater than 10%
- d. Changes in personnel involved in animal procedures;
- e. Changes in anesthetic agents or in the use or withholding of analgesics;
- f. Changes in methods of euthanasia;
- g. Changes in duration, frequency or number of procedures performed on the animal; or
- h. Changes in the degree of invasiveness of a procedure or discomfort to an animal

Protocol amendments with changes that are deemed “significant” will follow the standard protocol submission and review process.

Protocol amendments with changes that are not deemed “significant” based on a thorough evaluation by the IACUC Chair and Attending Veterinarian, can be approved administratively.

...change personnel on my protocol?

Use the DHMRI Personnel Amendment form found at: <http://dhmri.org/services-support/ncrcmembers-Portal>

Personnel, other than the Principal Investigator, can be added to a protocol by administrative action once they’ve completed the online training, enrolled in the Occupational Health Program, and attended a facility orientation session with the Center for Laboratory Animal Resources.

...enroll in the Occupational Health Program?

Complete the enrollment form at: <http://dhmri.org/services-support/ncrc-members-portal> and return it to the Director of Environmental Health and Safety at djhurley@northcarolina.edu.

...complete the training required to begin work with animals?

Contact the Program Administrator at dperalta@dhmri.org to enroll in the Collaborative Institutional

Training Initiative's online training program.

David H Murdock Research Institute encourages animal users to take full advantage of the breadth of courses offered beyond the required training.

The Center for Laboratory Animal Resources provides the mandatory Facility Orientation session. Contact the Program Administrator dperalta@dhmri.org for details and to register for this training.

...describe rodent breeding in my protocol?

The DHMRI IACUC Protocol Submission form has a section devoted to breeding. You will be asked to justify why you've chosen to breed animals and not purchase them from an approved vendor. Cost is not an acceptable justification. You will also be asked to describe the mating system, how the animals you breed will be used, and to justify the number of breeders.

Often, a separate breeding protocol may be appropriate.

...report a concern about animal care or use?

Animal research is a privilege and a trust. We are all stewards of their care.

If you should have any concern about animal care and use at David H Murdock Research Institute, tell someone in authority. Silence is complicity. If possible, discuss the situation with your supervisor.

Animal care and use concerns can also be reported to any IACUC Member, the IACUC Chair, Attending Veterinarian, any manager, or the IACUC Coordinator.

Concerns may also be reported anonymously. Call 866-494-3161 access code 4200.

...report a complication (anticipated or unanticipated) that occurs during an animal study?

Complications should be reported to the IACUC at iacuc@dhmri.org.

If the event involves an animal directly, contact iacuc@dhmri.org or 704-250-2672 or 336-757-0814.

...obtain the "IACUC verification/approval" that my sponsoring agency is requesting?

Contact the IACUC Office at iacuc@dhmri.org for a copy of your approval letter.

...attend the IACUC meeting when my protocol is under discussion to clarify any information that is contained in my protocol?

The schedule for IACUC meetings, usually held on the first Wednesday of the month, can be found at: <http://dhmri.org/services-support/ncrc-members-portal>. Let the IACUC Coordinator know beforehand that you plan to attend the meeting so that the Agenda can be arranged so that you do not have to wait indefinitely.

IACUC meetings are open, **but Investigators are required to leave the room while the IACUC deliberates and votes.**

What should I do if Federal agency representatives (not in the context of a formal NCRC-wide inspection) either arrives in my laboratory or notifies me of an impending site visit to review experiments involving animal studies?

The IACUC Attending Veterinarian, and the IACUC Chair are all able to assist you. In the event of an unannounced visit feel free to call the Attending Veterinarian at 704-250-2672 or 336-757-0814 or the Program Administrator at 704-250-2671 or 917-217-4431.