



The ACC Connection

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WELCOME to the ninth edition of the *ACC Connection*, a bi-monthly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. Our ninth issue is designed to familiarize animal users with the approval process the Animal Care Committee uses to review and approve animal care and use protocols and modifications.

New Animal Care and Use Protocols

Initial Investigator Steps. The first step of review of a new animal care and use protocol is for the PI to write the protocol. The form for new protocols submissions (it is necessary to use the current approved form) is located on the website (<http://clacc.uhc.edu/ACC/SubmittingProtocols.htm>). The new animal care and use protocol form should be downloaded from the website as a Word document. ***You must use the current protocol application form (failing to use the current form will result in the application being returned); therefore, it is to the PI's advantage not to keep the protocol form on their desktop but to use the protocol form on the website each time they write a protocol.*** Adequate review of your protocol depends on the Animal Care Committee (ACC), which is our institutional IACUC, receiving a thorough, well-written document that conforms to USDA and PHS policies as well as recommendations set forth by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and the *Guide for the Care and Use of Laboratory Animals*. This form was designed to comply with all applicable regulations; if properly completed, the PI should not have to worry about not complying with any regulations. Researchers should be aware that if they are using USDA regulated species (basically, any warm-blooded vertebrate animal except mice, rats, and birds), s/he ***must consult with the clinical veterinarian*** prior to filling out the protocol application form if s/he is going to be performing any procedures that have the potential to cause more than momentary pain or distress to the animals- this is a requirement of the Animal Welfare Act.

The second step is for the investigator to submit the protocol in the correct manner. All protocols must be submitted as Word documents. They must be email attachments sent to the ACC office (ooacc@uchc.edu). ***The ACC office will not accept hard copies as valid submissions.*** Please note that this is very different from IRB requirements. The ACC office will not accept PDF files. The investigator must submit the protocol application by the deadline for the ACC meeting s/he wants the application to be reviewed at. The dates of all ACC meetings and respective deadlines are posted on the ACC website (<http://clacc.uhc.edu/ACC/SubmittingProtocols.htm>). It is the responsibility of the Principal Investigator to submit the appropriate applications by the deadline (generally, the 10th of the month for that month's meeting).

Initial ACC Office Steps. The first thing the ACC office will generally do is review the application for completeness. If the application is not completely filled out, it will be sent back to the Principal Investigator with a list of items that need to be corrected or completed. The application, as submitted, will not be processed further and the PI will be notified of this.

If the protocol application is complete, it will then typically be reviewed by the ACC office to see if there are any major problems with the document. If the protocol application contains major errors (typically those associated with compliance with federal, state, or institutional laws, regulations, and/or policies), it will be sent back to the Principal Investigator with a list of items that need to be corrected. The application, as submitted, will not be processed further and the PI will be notified of this.

When the ACC Office has received a complete document, it is next looked at to decide what method of review the protocol will have. The ACC has a policy on using the Designated Member Review (DMR) system to review new protocol submissions (<http://clacc.uhc.edu/ACC/Policies/DMRnewprotocols.htm>). Those applications which meet the criteria for a DMR review will be processed for such a review. All other applications will require a full committee review. The ACC Office will assign primary (scientific), veterinary, and safety reviewers to the protocol application. These individuals are

sent a copy of the protocol application along with information on the type of review the applications has been assigned, what ACC meeting the application will be reviewed at (if applicable), and what the reviewers need to do.

The ACC Office will let the Principal Investigator know if anyone involved with the protocol needs core animal training and/or enrollment in the occupational health surveillance program. ***If you do not hear from the ACC office within 2 days of submitting your protocol application, please call the ACC Coordinator at x4129 or contact the ACC Office at ooacc@uchc.edu.***

Initial ACC Committee Steps. If a protocol has been assigned to a DMR review, the reviewers are responsible for reading the submitted protocol application and reviewing it for content. They send a review of the protocol to the ACC coordinator. The coordinator will compile all the reviews and send the PI the ACC Initial Review of the protocol along with the status of the protocol after review (approved, minor modifications required, or deferred to full committee review).

If a protocol has been assigned to a full committee review, the reviewers are responsible for reading the submitted protocol application and reviewing it for content. They will then present the protocol at the ACC meeting the protocol was assigned to (based on the submission date of the protocol application to the ACC office). After the ACC meeting, the ACC coordinator will send the PI the initial ACC review of the protocol along with the status of the protocol after review (approved, minor modifications required, disapproved, or deferred).

Second Investigator Steps. Once the PI receives the initial ACC review of his/her protocol, it is their responsibility to respond to the ACC review. The ACC requires that the PI detail, in memo form, a response to each item in the review which is given to him/her. The ACC also requires a revised protocol be written and submitted which incorporates all the changes detailed in the memo. Both the memo and the revised protocol must be Word documents submitted to the ACC office as email attachments. The PI has 3 months in which to submit a revised document; after that time, the protocol may be considered to be withdrawn by the PI unless a written request for more time has been submitted to the ACC office.

Second ACC Office Steps. Once the PI memo and revised protocol are received by the ACC Office, it is processed as required by ACC Policy (<http://clacc.uchc.edu/ACC/Policies/Protocol%20review.htm>). If an initial review was “minor modifications required”, the subsequent review is via DMR; if the initial review was deferred (even if the initial review was via DMR), the subsequent review is by full committee review. The memo, the revised protocol, the initial ACC review, and the initial protocol get sent to the reviewers of the protocol for review. This process may be repeated indefinitely until the reviewers are satisfied with the protocol application and it can be approved.

Second ACC Committee Steps. The reviewers will get the above information and it is their responsibility to review the changes and let the ACC coordinator know if the changes are acceptable to them or if additional changes are required. Once all reviewers are satisfied with a protocol, it can be approved.

Third ACC Office Steps. Once the ACC coordinator receives a recommended approval from all the reviewers of the protocol, the protocol is reviewed to make sure that all individuals listed as using laboratory animals have completed animal care training and have enrolled in the occupational health surveillance program. If all aspects of the protocol are satisfactory, the protocol is then ready to be approved by the ACC via the coordinator. A PDF document of the final version of the protocol will be generated by the ACC office and sent to the PI for an electronic signature. Once the signed copy is sent back to the ACC office, the coordinator will generate the final approved copy of the protocol (which is placed in the official ACC file and sent to the PI) and an approval letter which is sent to the IO for signature. Once the signed approval letter is received from the IO, it is mailed to the PI along with a “Protocol Assurance of Compliance Signature Sheet” for the protocol. This compliance sheet must be signed by all personnel associated with the approved protocol and stay with the approved copy of the protocol (sent to the PI by the ACC office) kept by the PI; if the protocol has any approved medications to add personnel, these individuals must be listed on the compliance signature sheet by the PI and signed by each individual added once those subsequent modifications are approved by the ACC.

Modifications to Approved Protocols

Modifications to approved animal care and use protocols are handled much in the same way as new animal care and use protocol applications. The modification form (which should be filled out completely) is available on the website (<http://clacc.uchc.edu/ACC/SubmittingProtocols.htm>) and must be submitted in the same manner as a new animal care and use protocol application. The review process is, in effect, identical to the review process of new animal care and use protocol applications. Most modifications are handled via DMR reviews; however, in some instances, modifications require a full committee review. In rare instances, a modification may require a new protocol submission.

Frequently Asked Questions

How long does it take to approve new animal care and use protocol applications?

Unfortunately, the true answer is- It Depends. Approval depends upon the review of the protocol application and adequate review of the protocol application depends on the ACC receiving a thorough, well-written document. The document must conform to USDA and PHS policies as well as recommendations set forth by AAALAC and *The Guide for the Care and Use of Laboratory Animals (The Guide)*. **Average time for new protocol approvals from the time of committee review (not the time of submission) until approval is 8 weeks.** Complicated protocols (e.g., surgical protocols, protocols with deviations from *The Guide*) may take even longer. Fairly simple protocols (e.g., tissue harvest protocols with no experimental manipulations of the animals) may take less than a month to be approved.

What if I have questions on filling out the protocol application form?

The ACC provides a set of instructions designed to help you to fill out the animal care and use protocol application form. These can be found on the website (<http://clacc.uchc.edu/ACC/SubmittingProtocols.htm>). Researchers should print out these instructions and refer to it when filling out their protocol application forms. If you still have questions, you should contact the ACC office (ooacc@uchc.edu) for assistance.

How long does it take to approve modifications to approved animal care and use protocols?

Again, the true answer is- It Depends. **Modifications to add adequately trained and qualified personnel typically take approximately 10 days** (to allow for enrollment in the occupational health surveillance program which they must do). Other modifications typically take a longer amount of time. The ACC tries to approve most modifications via the DMR system (please review our policy on this system) in order to shorten the amount of time it takes to approve modifications, but not all modifications meet the requirements for this review system. Modifications that meet the DMR requirements typically take approximately 10 days to get approval. Modifications that must go to full committee review typically take 4 weeks from time of committee review to get approval.

Why does it take so long to get approval of protocols?

The protocol application itself is not the only determinant of when a protocol is approved. If the research involves the use of hazardous agents, a safety protocol may have to be in place prior to ACC approval. If transgenic animals or recombinant DNA are being used, IBC registration and/or approval may have to be in place prior to ACC approval. All animal users must be up-to-date in animal training and enrollment in the occupational health surveillance program prior to protocol approval. All of these requirements must be fulfilled prior to the animal care and use protocol being approved by the ACC.

Are there any guides to help Principal Investigators prepare animal care and use protocols?

Absolutely. Contact the ACC Office if you would like a copy of "Working with the IACUC: Writing an Animal Care and Use Protocol" which was written by AALAS. This will give the investigator a lot of ideas on what is needed in an application. In addition, check out the information on the web on how to fill out the protocol; often, delays are caused by the PI not knowing what type of information, or amount of detail, is actually required in various sections of the protocol application. This document is on the website where the protocol forms are located. If you are performing procedures that have the potential to cause more than momentary pain or distress, contact the ACC Office to get a copy of a handout titled "Meeting the Information Requirements of the Animal Welfare Act" which can help the PI to perform this requirement correctly. This does not have to be limited to USDA regulated species only as the search for alternatives to painful procedures is applied to all animals.

Upcoming Training, July 2007 – August 2007

New Animal Users Initial Basic Core Training

Monday, July 23

9:00 am – 12:00 pm

Building 20 conference room

Monday, August 20

9:00 am – 12:00 pm

Building 20 conference room

New Institutional, State, or Federal Regulations

Institutional

ACC Policy

5/31/07

Policy on Animal Holding in PI Laboratories. To view policy, go to:
<http://clacc.uchc.edu/ACC/Policies/AnimalHolding.htm>.

State

None

Federal

H.R. 2193

5/7/07

Submission of this bill to Congress to amend the Animal Welfare Act to prohibit the use of animals for marketing medical devices, to increase the penalties for violations of the Act, and for an annual report to be submitted to Congress regarding all USDA registered research facilities.



Next Issue:

Researcher Responsibilities

CONTACTS

ACC Coordinator / Research Compliance Monitor
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AVP for Research Administration / Institutional Official
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