IACUC Update

Institutional Animal Care and Use Committee
The University of Texas at Austin

Welcome to Your Newly Designed IACUC Update

The IACUC Update has a new look. Please send feedback, comments, and suggestions to: IACUC@austin.utexas.edu

New Procedures for Retiring or Closing a Protocol

The IACUC procedures for closing out protocols have recently been formalized. When an investigator contacts the Office of Research Support requesting to close/retire a protocol, the investigator must confirm the following information:

1) The PI must confirm that no animals remain on The University of Texas at Austin campus under the protocol number. If animals remain, the PI must make arrangements for the disposition of those animals (either euthanize the animals or transfer them to the ARC Holding Protocol).

2) The PI must provide a statement that it is his/her responsibility to communicate to all protocol personnel that the protocol is being closed and the no further animal work may ensue.

Once this information is received, the Office of Research Support will officially retire the protocol.

Welcome Back Everyone

A new academic year is here and there may be new faces in the lab. Be sure to submit protocol modification(s) to remove folks that no longer work on protocol(s) and to add new lab members.

A Note on Protocol Personnel

It is necessary for the IACUC protocol to list **EVERY** person who is actively handling, manipulating, or performing procedures on live vertebrate animals. Please see the attached "**FAQs about Protocol Personnel**" for more information. These FAQs have also been posed on the FAQs section of the IACUC website.

eProtocol Tips of the Month

When will my protocol be reviewed?
IACUC meetings (Full Committee Reviews, FCRs) are held once a month. The majority of the review of your protocol occurs in the weeks PRIOR to the FCR. This is why the eProtocol deadline is earlier than the paper protocol deadline. This allows the IACUC to spend more time discussing your protocol and not discussing incorrect dosages or typographical errors.

Why was my protocol RETURNED? The Vice President for Research has established the Office of Research Support (ORS) to serve as an administrative office to support the IACUC. The ORS receives protocols and screens them for compliance with administrative requirements, readablility, and completeness. Protocols are usually returned because questions have not been answered, additional details are required, etc.

The next IACUC Full-Committee Review (FCR) is **October 12, 2009**.

The deadlines to submit materials for review are:

➢ eProtocol: **September 18, 2009**
➢ Paper: **September 30, 2009**

Frequently Asked Questions about Protocol Personnel

Is it necessary for the IACUC protocol to list EVERY person that will be involved with the proposed research project?

Yes. The names of anyone who is actively handling, manipulating, or performing procedures on live vertebrate animals must be provided to the IACUC either in the original protocol submission or in a formal modification sent to the committee.

Is there a legal requirement for this, or is it just a campus policy?

It is a specific regulatory requirement for all institutions that receive federal funding from NIH. As a part of the evaluation of proposed research projects during the protocol review process, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals requires the IACUC to assess whether personnel conducting procedures are appropriately qualified and trained in those procedures[1]. Similar requirement are found in the regulations promulgated under the federal Animal Welfare Act, and in the NIH Guide for the Care and Use of Laboratory Animals[2]. As shown in the model IACUC protocol template provided by NIH Office of Laboratory Animal Welfare (OLAW), there is a requirement for the protocol to list the names of "all individuals authorized to conduct procedures involving animals" under the protocol[3].

Is it a serious issue if personnel are performing studies with animals and they aren't on the protocol?

Yes it is. OLAW requires that significant instances of noncompliance be promptly reported to federal agencies, and unlisted participants is one of the examples of a "significant" deficiency. The guidance states that "participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained" is a reportable offense[4]. If such a situation is identified, the IACUC must perform a review of the situation and issue a report to the Vice President for Research, who then is required to formally report the findings to NIH, along with the name of the PI and a listing of any NIH funded studies that were involved.

Can't transient personnel such as students be excused from this requirement?

There is no ability for the IACUC to extend any blanket exemptions for this requirement, but there are ways that student participation can be managed. For example, undergraduates that have classroom contact with research animals as part of a wet lab session are under close supervision by the instructor and/or experienced TAs at all times. If an IACUC protocol is submitted which a) makes it clear that this is a teaching situation, b) explains how students will be closely supervised, c) describes how the students will be given targeted training in ethical use of research animal at UT, and d) lists the instructors and TAs that will be responsible and shows that they have fulfilled IACUC training requirements, then the individual course participants do not need to be individually listed.

The situation with rotating graduate students is somewhat different because as they become active in a lab they will be expected to work independently and also to perform more complicated procedures than would be included in undergraduate education. However, streamlining of the process is still possible, especially if those responsible for designing and coordinating graduate programs take animal use into consideration. If it is likely that some or all of the graduate students in a particular training program will eventually rotate through a lab which uses animals, then it is suggested that these individuals be instructed to take the online training modules

in advance of their rotation. Graduate program coordinators can also educate students on the need to be added to protocols when they rotate to a new lab, and might even be able to provide the PI some administrative assistance to expedite the process. Finally, if a large proportion of the students in a particular program will be predictably be rotating through animal labs, there would be an opportunity to create a specific teaching protocol structured so that it would cross-reference the IACUC approved protocols of a number of potential rotation projects, which would minimize the number of protocol modifications needed to cover the rotation students over time.

Doesn't adding personnel take a long time for the IACUC to approve?

No, it is accomplished by filling out a short modification form[5]. In order to help make this as simple as possible, the OLAW guidance was revised in 2003 to allow changes in personnel (other than the PI) to be considered a "minor" change which can be approved administratively rather than requiring a full IACUC protocol review. The IACUC is still required to assure that all such personnel are a) appropriately identified, b) adequately trained and qualified, and c) enrolled in applicable occupational health and safety programs[6]. The basic training requirements for being added to a protocol can be fulfilled by turning in a short occupational health questionnaire form, registering online for an orientation session, and taking a few online training modules. A complete description of how to fulfill training requirements can be found on the IACUC website[7].

What training is required to add personnel to a protocol?

Please visit our **Training** page for more information: http://www.utexas.edu/research/rsc/animalresearch/training.php

Who can I contact to discuss training issues and the process of adding persons to a protocol?

Please call the IACUC Program Coordinator at 475-8650 with any questions.

How do I add a new employee to my protocol?

Either a Modification Form can be completed which includes the person's name, EID, training experience and training record (dates they attended ARC Orientation, Nurse Interview or completed web-based training) or an email can be sent including this information to the IACUC Program Coordinator at **iacuc@austin.utexas.edu**.

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(1) See section IV.C.1.f in the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* **http://grants.nih.gov/grants/olaw/references/phspol.htm**
(2) As summarized in section C.2.e. (Personnel Qualifications) in the *ARENA/OLAW Institutional Animal Care and Use Committee Guidebook* **http://grants1.nih.gov/grants/olaw/GuideBook.pdf**
(3) See section A, "Administrative Data" of the *Sample Animal Study Proposal* **http://grants.nih.gov/grants/olaw/sampledoc/animal_study_prop.htm**
(4) Communicated in the OLAW notice "*Office Of Extramural Research Revised Guidance Regarding IACUC Approval Of Changes In Personnel Involved In Animal Activities*" **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-046.html**
(5) A copy of the current IACUC *Modification Form* can be downloaded here: **http://www.utexas.edu/research/rsc/animalresearch/forms.php**
(6) Communicated in the OLAW notice "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html**
(7) A training checklist can be found on the IACUC website at: **http://www.utexas.edu/research/rsc/animalresearch/training.php**