

Letters to the Editor

Innovative, But Not Compliant

To the Editor:

The NIH Office of Laboratory Animal Welfare (OLAW) and USDA/APHIS, Animal Care (AC) have reviewed the February 2001 *Lab Animal* article, "An Innovative IACUC Protocol System" by Katie Traxel [30(2):32-35]. We recognize the many positive innovative and burden-reducing elements in the system (for example, the Investigator's Web). We also recognize that there are circumstances under which the PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*) and/or the Animal Welfare Act Regulations (AWAR) do not apply. Nevertheless, both OLAW and AC find elements of the system, as described, to be noncompliant with the federal requirements for protocol review.

Because many readers of *Lab Animal* are subject to these federal requirements, we believe that clarification of these inconsistencies is essential. Relatively minor modifications of the described system could be made to make it fully compliant.

Under the PHS *Policy* and AWAR there are only two protocol review models—full-committee review and designated-reviewer review. The "Innovative IACUC Protocol System" (IS) appears to be a hybrid of these two review methods, and fails to fully satisfy the requirements of either system.

The IS does not meet the full committee review model because full review must occur in real-time and with a convened quorum of the IACUC participating (see *ILAR Journal* 37(4):190-192; <http://grants.nih.gov/grants/olaw/references/ilar95.htm>).

Under the designated-reviewer model, all members must be given the opportunity to call for full-committee review of a given protocol. This step appears to have been omitted in the IS. Designated reviewer(s) may only "approve, require modifications in (to secure approval), or request full committee review..." Designated reviewers do not vote. If the IS is attempting to follow the designated reviewer model, with all members being treated as designated reviewers, then every member must respond with one of the above three options. Under these circumstances, a quorum of designated reviewers approving the

protocol is not sufficient and approval by all is required. If modification occurs at any stage of the review, all designated reviewers must see and approve the changes.

Other elements of the article require further clarification to determine whether they are compliant. It is unclear what role the IACUC Coordinator has in editing the IACUC's comments. Modification of the official record of review would seem to be highly inappropriate. Regarding the final approval role of the Coordinator, if it is simply administrative ("clicking the button"), then we recommend it be so stated.

The statement that the Coordinator may assign the protocol to veterinarians or safety personnel implies that these individuals might not be involved otherwise, and that the Coordinator would be referring the protocol to a veterinarian other than the one on the IACUC. Elsewhere, it is stated that protocols are not designated to specific reviewers. This appears to be contradictory.

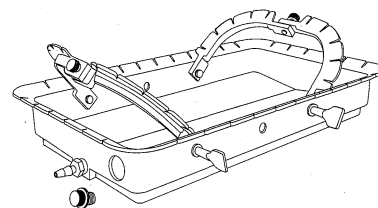
In order to modify the IS to conform with federal requirements, it is first necessary to clearly recognize which mode of review (full or designated) is being emulated. The appropriate procedures, in the required sequence, can then be designed into the system. In this case, such modifications would appear to be minor and would not substantially diminish the intended benefits of the IS. We would be pleased to collaborate in the design of model electronic protocol review systems that are consistent with PHS/USDA requirements.

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Office of Laboratory Animal Welfare
W. Ron DeHaven, DVM, Deputy
Administrator, USDA, APHIS, Animal Care

Editor's note:

As stated above, the article in question was meant to showcase how one facility is attempting to reduce time and effort through an innovative online system. We regret that editing changes might have created the impression that the system is fully compliant, and appreciate that OLAW and USDA/APHIS took this opportunity to clarify federal policy and regulation regarding this important matter.

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An Innovative IACUC Protocol System

Katie C. Traxel, BS, RLATG

The author describes a web-based system that has decreased paperwork and protocol approval time, while making protocols available for viewing by the research community.

As is the case in all institutions that abide by the guidelines outlined in the Animal Welfare Act and the *Guide for the Care and Use of Laboratory Animals*, protocols at Abbott Laboratories involving animals require approval by the Institutional Animal Care and Use Committee (IACUC). This approval process had evolved from blank paper forms to electronic templates, which helped to guide the investigators by including multiple answers in drop-down menus and tab-stop fields. While the guidance provided by the templates was an improvement for the investigators and the IACUC, the review and approval process still required distribution of multiple paper copies to each Committee member. Additionally, once approved, the protocols were not readily available for review by the research community.

We decided that web-based technology could provide us with an improved system for handling the protocol submission and approval process, which could save time and allow for data sharing. We consulted with a local database design company with the objective of improving this process for the investigators and the IACUC by mak-

ing the protocols available online. The consultant recommended a web-based interface to a database and helped us design our current system, which we describe here.

The Investigator's Web

When an investigator logs on to the IACUC protocol system page on our corporate intranet, she is presented with a number of options, including searching for protocols by key words, title, or number; amending one of her own protocols; or creating a new protocol (Fig. 1). Once she chooses to create a new protocol, the system takes her through a series of questions. Each step in the protocol is a separate web page, and as the investigator moves on to the next page, the information is saved to the database.

Different questions direct the investigator to different types of answers. In most cases, the system guides the investigator to answer questions by asking her to choose from one or more radio buttons or drop-down menus, e.g., when asked to justify the number of animals requested, the investigator can choose from the following: 1) group size to achieve statistical significance; 2) repetitive trials planned, best

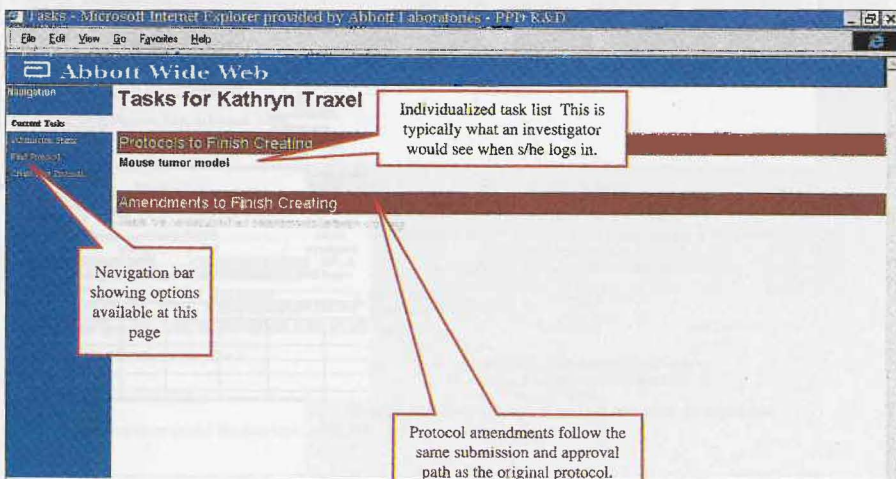


FIGURE 1. The investigator's log on page.

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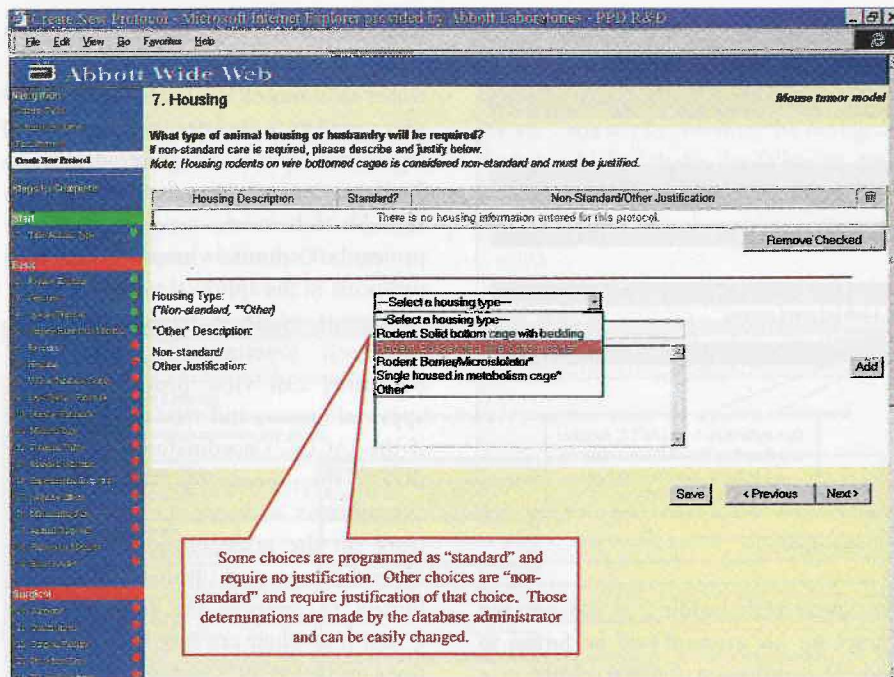


FIGURE 2. The navigation bar at the left shows completed steps with a green dot, uncompleted steps with a red dot.

guess of 12-month use; 3) repeated use of animals in “pool,” number allows rest between uses; and 4) other (define). In areas where text is the most appropriate response, free text boxes are available for input.

As the investigator moves through the protocol, a navigation bar shows each completed step with a green dot and each as yet uncompleted step with a red dot (Fig. 2). The investigator can use the navigation bar to jump from step to step and change or review any step in the protocol at any time. The system recognizes different components of the protocol and includes or excludes questions based on information provided by the investigator, *i.e.*, one question asks if surgery will be performed. If the investigator chooses “yes,” a whole set of surgery questions are included in the navigation bar (Fig. 3). The investigator can exit the system at any time and return later to pick up where she left off. Once the protocol is completed, the investigator clicks a button to electronically “submit” the protocol to the IACUC. At this point, the system locks out everyone but the Committee from access to the protocol and will not permit

any changes to it. The investigator is also prompted to print an assurance page, which she must sign and submit as a paper document.

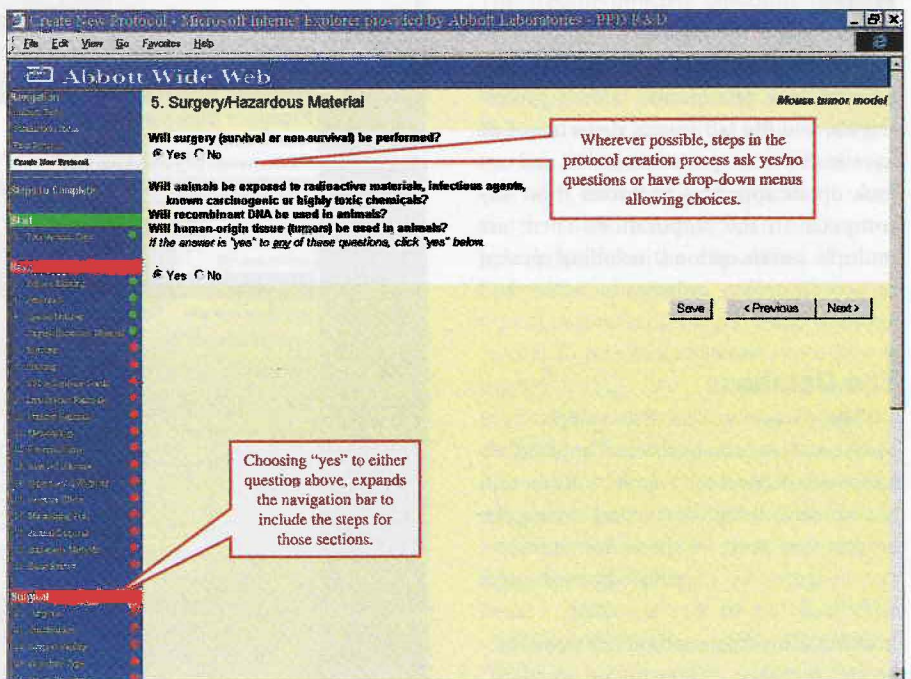


FIGURE 3. A “yes” answer on the Surgery/Hazardous Material page will result in surgery-related questions on the navigation bar on the left side of the screen.

The IACUC's Web

A submitted protocol is automatically routed to the IACUC. Committee members log on to the same page on the intranet and a list of protocols awaiting their review appears (Fig. 4). The Committee members can read the protocol online, comment on the protocol, and indicate their approval or disapproval. Rather than designating specific reviewers for each protocol, at minimum, a quorum of Committee members must approve each protocol. The system allows IACUC members access to comments made by other Committee members. The comments are stored as a permanent part of the protocol, and the Committee members continue to have access to the protocol and all the comments and discussion until final disposition of the protocol. If a protocol is returned for revision, it appears on the investigator’s task list.

The IACUC Coordinator's Web

The IACUC Coordinator directs the protocol through the approval process. He views the Committee’s comments and has access to edit them during the online dis-

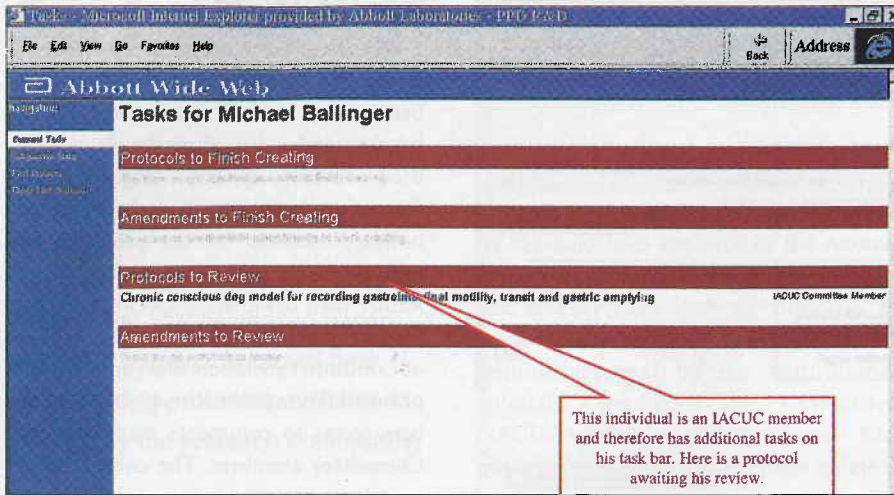


FIGURE 4. Protocols awaiting action by an IACUC member.

cussions. The Coordinator can electronically add approval steps, i.e., safety or additional veterinary review. He keeps track of the protocol's progress and, upon direction from the Committee, can send the protocol back to the investigator for revision. He also clicks the button that approves the protocol (Fig. 5).

The Research Community's Web

We define the "research community" as those participating in a protocol. Investigators, technicians, safety professionals, and the lab animal department all have access to the protocol system, and can look up all approved protocols from any computer in the corporation. There are multiple search options, including species, surgery, restraint, investigator name, and approval dates (Fig. 6).

The Database

The backbone of the system is a Microsoft® Access database. The database has two functions: storing the information contained in the protocol, and storing the criteria that generate the website options. For instance, we consider shoebox cages with bedding to be "standard" rodent housing. The database administrator designates that type of housing as "standard" in the database (Fig. 7). An investigator who chooses something other than shoe-

box cages with bedding as the housing choice on his protocol will be forced to provide justification for that choice in a text box on the website. The database administrator can change shoebox cages to "non-standard" and designate something else as "standard" and the website would then force the investigator to justify shoebox cages.

The database also stores the list of

users who have access to the system and their passwords. The database administrator determines what roles these users play, and then dictates the user's privileges. Investigators can create protocols. Participating personnel, typically research technicians, can view approved protocols. Committee members can view protocols in the approval process and the comments of their fellow committee members. Veterinarians and Safety Personnel can view protocols in the approval process and view the comments if the IACUC Coordinator has assigned them the protocol. The IACUC Coordinator oversees the Committee's work on the protocol, adds or deletes approval steps, and ultimately clicks the button to approve the protocol. The Committee Chair can take over the functions of the IACUC Coordinator and also functions as a Committee Member. As personnel change, the database administrator can easily add people to the different roles or change an individual's role and thereby change her privileges in the system. Potentially, the database administrator could "tamper" with protocols, so

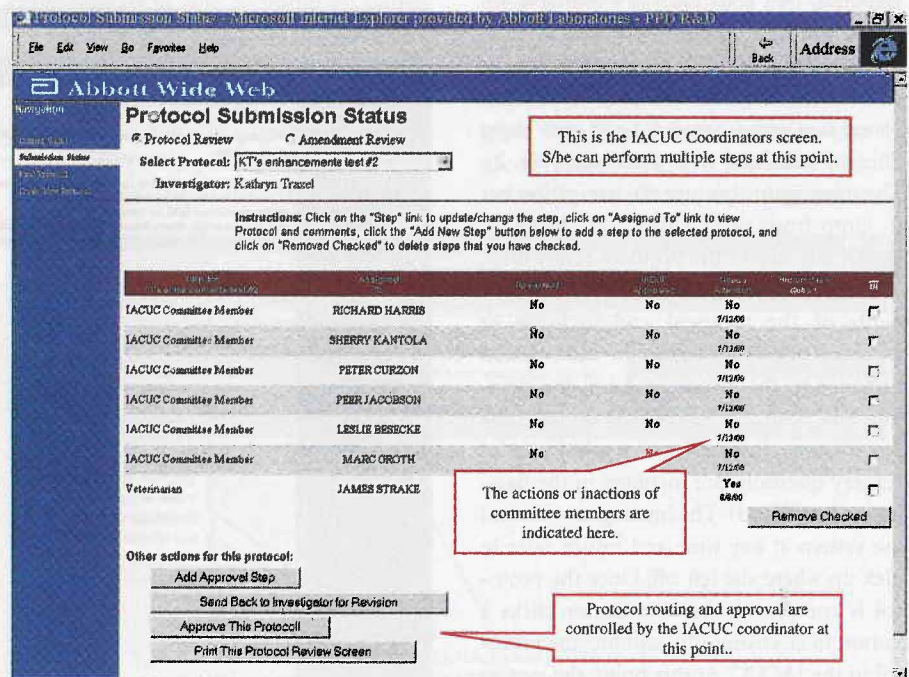


FIGURE 5. The IACUC Coordinator's page. The Coordinator can follow the progress of the Committee's actions on any protocol and can approve the protocol on screen.

he is therefore in a position of trust.

This system is as secure as any password-based system can be. The entire system is behind the corporate firewall and cannot be accessed by anyone outside the organization, besides the outside IACUC members who are listed as consultants and can access the intranet remotely from their homes.

Future Enhancements

As soon as the system was operational, users had suggestions for future features. We are currently beta-testing the next generation, which includes the following new features:

- Allows the user to change her own password;

- Allows multiple viewers of a protocol during the creation phase. In the current system, only one person creating the protocol can view it while it is in process. The next version will allow the investigator to specify a list of people who can view the protocol up to the time it is submitted;
- Allows the investigators a text box for comments during revision. Currently, when a protocol is sent back to the investigator for revision, she can only change the data, but cannot make any comments. The next version will give the investigator a comment box;
- Allows the IACUC a second set of comments. Following revision, an investigator resubmits the protocol. The new version will provide a separate space for the IACUC to make post-revision comments.

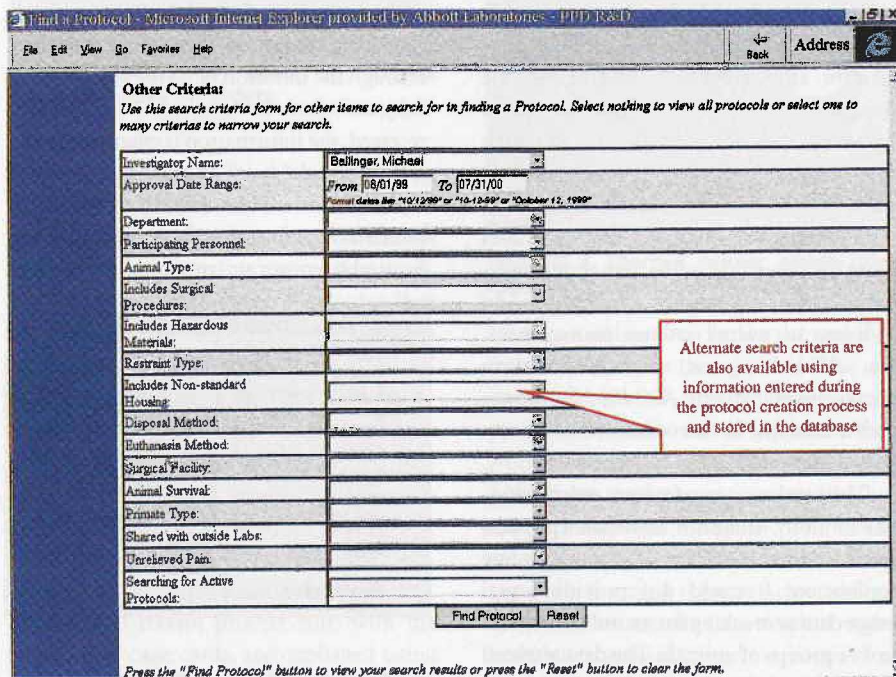


FIGURE 6. Information on an approved protocol is available to all protocol participants.

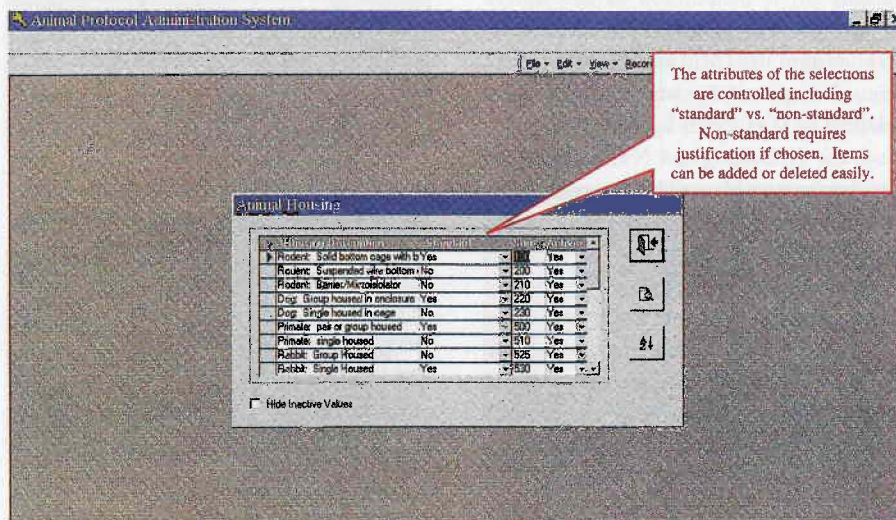


FIGURE 7. "Standard" options are programmed into the database. Researchers may select "standard" options or must justify using "non-standard" choices.

Conclusion

Both the investigators and the IACUC have responded favorably to this new system. There has been a significant reduction in paper moving through the corporation. Most protocols can now be approved in less than half the time previously required. The website-directed questions help the investigators provide the answers the IACUC requires for its decisions. The in-house research community now has the ability to easily view what other investigators are doing and, we hope, will collaborate with them to avoid redundant work and to share techniques. An unexpected benefit has been the stimulation of more Committee discussion online than was typical in meetings.

The Committee still meets regularly to discuss IACUC policies and procedures, inspection results, and any protocols the Committee believes require face-to-face discussion. Hard copies of Committee members' votes and the investigator's assurance are kept and filed with a hard copy of the protocol.

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