There are three very important articles in this quarter’s newsletter, which may affect your research. Please make sure to read these articles!

Of Interest to Those Using Dogs and Cats in Teaching and Research; NAS Report on Use of Random Source Dogs and Cats

The National Academies of Science (NAS) has just announced the release of a report covering the use of random source dogs and cats in biomedical research.

This report titled Scientific and Humane Issues in the Use of Random-Source Dogs and Cats in Research finds that random source dogs and cats may be desirable and necessary for certain types of biomedical research, but that it is not necessary to acquire them through Class B dealers, as there are adequate numbers of such animals from shelters and other sources.

The report was commissioned by the National Institutes of Health (NIH in response to a request by Congress in the FY08 appropriations bill.

Bill Ferner, D.V.M., Dipl ACLAM
Director Laboratory Animal Program

Overview of Report: Random source dogs and cats -- those that come from the general population, rather than being bred specifically for biomedical research -- can be valuable models for studying certain types of diseases. Dealers who buy and sell random source animals, rather than breed them (known as Class B dealers), are licensed by the US Department of Agriculture to ensure animal welfare and appropriate acquisition of the animals, but without adequate enforcement, some fear that lost or stolen pets could end up in laboratories, or that the dealers may not uphold proper standards of care. In response to a request by Congress through the National Institutes of Health (NIH) for a critical evaluation of the need to use random source dogs and cats from Class B dealers in NIH-funded research, this report finds that random source dogs and cats may be desirable and necessary for certain types of biomedical research, but that it is not necessary to acquire them through Class B dealers, as there are adequate numbers of such animals from shelters and other sources.

(As reported in the National Association for Biomedical Research Alert dated May 29, 2009.)

A full preview of the report can be read free online at:
Special Authorizations and Limited Approvals

Purdue University’s Animal Welfare Assurance renewal was recently submitted to the U.S. Public Health Service. During the review of the document by the Office for Laboratory Animal Welfare (OLAW), it was determined that special authorizations for changes in procedures can no longer be given by the PACUC Chair or the LAP veterinary staff. In the past, under special circumstances, authorization to make changes in animal care and use activities could be granted prior to receiving approval of an amendment via the designated review pathway or review at a meeting of the full PACUC. Such special authorizations could only be granted when they promoted animal well-being. For example, there could be emergency situations (e.g., equipment failures) that required animals to be moved to locations not listed on a protocol or if waiting to obtain immediate approval to change anesthesia or post-operative analgesia would put the animal’s welfare at risk. In all cases, these changes were later discussed by the PACUC at a meeting and were followed up by formal amendments from the investigators that underwent PACUC review.

Since special authorizations to make these changes can no longer be given, it is very important for investigators to consider alternatives during the writing and submission of their protocol applications. For example, one might indicate alternative anesthetics if there appear to be potential problems with the first choice. Ranges of anesthetics could be given since some species of animals may be less susceptible than others. Similarly, a variety of potential analgesics could be presented. For surgical procedures, drugs could be listed for use only in emergency procedures to deal with problems such as hypotension or excessive secretions. The burden will be on the P.I. to think ahead about contingencies. PACUC and LAP will continue to try to assist with this during the protocol review process.

It was also determined during OLAW’s review of the recently submitted Assurance document that the PACUC can no longer approve part of a project (Limited Approval). In essence, OLAW indicated that the PACUC can only approve a protocol or disapprove it. Previously, our Assurance allowed PACUC to approve certain uses of animals (e.g., some experiments, some procedures, some species, and some number of animals) but not all uses that are described in the protocol. What this change in the Assurance means is that investigators need to think carefully about how they design their studies and write their protocols. For something that is very new or novel, and perhaps even somewhat risky, one may wish to use two or three animals in a study to determine proof of principle, evaluate whether or not a particular surgical procedure can be done, assess which of two species might be the most useful, etc. This initial study could be submitted to PACUC as a protocol to be reviewed. If approved and the experiment or study is successful or the procedure proves to be feasible, then the investigator can file an amendment to expand the study to include more animals. In fact, the case could be made that the preliminary study demonstrates that the procedures work well and thus expedite the review process for the amendment. As always, PACUC will work with investigators on both the original protocol and amendment to facilitate their approval and shorten potential experimental down time.

Gary P. Carlson, PACUC Chair
As we meet during our PACUC-LAP Orientation sessions with new staff and students who will utilize vertebrate animals in their research, teaching, and testing programs at Purdue, there are several important “take-home” messages we try to deliver.

Two of these are the importance of everyone (i) being familiar with the protocol, approved by PACUC, that describes their project or teaching activity and (ii) being aware of how to address concerns about animal care and use if they should arise.

(i) The protocol approved by PACUC, with all its amendments, defines in detail the scope of research and/or teaching procedures utilizing vertebrate animals that you may implement as part of a teaching or a research activity at Purdue. All experienced with research recognize that it is inherent in the research process that plans and procedures evolve. Experiments should always provide new insight. Sometimes this insight informs the investigator of a weakness in the experimental design or a specific procedure; sometimes the insight exposes the need for a previously unanticipated control or entirely new question requiring empirical resolution. However, federal regulations and Purdue policy require that before any new procedure, or other substantial change in a protocol that has the potential to impact animal welfare, is initiated, that change must be reviewed and approved by PACUC. Implementing changes in protocol without prior approval by PACUC may place both the investigator and the University in jeopardy due to non-compliance with federal regulations. One of the best ways to ensure this does not happen is for all personnel to be familiar with the approved protocol.

How can an investigator know what represents a substantial change in a protocol requiring an amendment? PACUC offers the following guidance to help in addressing this question. If the change would lead to a different response to one of the questions asked on the protocol form (PACUC Form 1), it requires an amendment. A list of examples of changes requiring an amendment is provided below.

Changes in the overall objectives of the approved studies.
Changes from non-survival to survival surgery or vice-versa.
Changes that increase the pain or discomfort experienced by animals (e.g., increased restraint, restrictions on food or water intake, exposure to noxious or hazardous stimuli or materials).
Changes in the anesthetic agent(s) or dose(s) or the method(s) of administering of anesthetic agents.
Changes in the use of analgesics.
Changes in the use of sedatives or tranquilizing drugs.
Changes in the method of euthanasia.
Changes in the species used.
Increases in the number of procedures performed on an animal.
Modifications to a surgical procedure.
Changes in the duration of a procedure that is performed on an animal (e.g., chronic rather than acute procedures or vice-versa, length of a behavioral test session).

Changes in the housing or husbandry of animals or the site the experimentation will take place in.

Changes in the personnel involved with the project. Changes in the frequency of procedures (e.g., blood sampling, drug administration, tissue biopsy, exposure to stimuli, number of repeated behavioral tests).

Changes in the invasiveness of a procedure (e.g., utilized a catheter rather than a needle to obtain fluid samples, injected rather than administered an oral form of a drug).

If you are still unsure, please call the PACUC office at 494-9163 and ask.

(ii) A critical responsibility shared by all who utilize vertebrate animals in research and teaching is ensuring animal welfare. Whenever we observe an example of animal care or use that we believe may pose a risk to the health or safety of animals, we have a responsibility to address it. The first, and often the only necessary, step in addressing concerns is to speak with the individual(s) responsible for the animal or activity that is the subject of your concern. Often, concerns are a reflection of a misunderstanding or partial understanding of what we have observed. However, if we are unable to resolve the concern by this route, it is very important that these unresolved concerns be reported to PACUC. PACUC’s goal will always be to remediate the concern and protect the animal(s).

How do you report concerns to PACUC? Concerns should be reported to Lisa Snider (ldsnider@purdue.edu), PACUC Administrator, Gary Carlson (gcarlson@purdue.edu), PACUC Chairperson or to Bill Fener (ferner@purdue.edu), LAP Director. All reports of concern will be accepted in strict confidence and you may report your concern anonymously if you wish; however, this is less desirable since it precludes our ability to reach you if clarification were required. When a concern is received, PACUC will verify the situation, usually with the help of the LAP veterinarians, and take whatever steps are necessary to protect the animals involved. Generally, this is accomplished by providing information or training to staff responsible for the animal(s). Concerns and the actions taken to resolve them are then reported to the full PACUC, so that the committee can determine if all steps needed to resolve the concern have been taken. Only with your help, can we ensure the humane care and use of vertebrate animals at Purdue.

Upcoming PACUC Meetings

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<td>July 15</td>
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