Abstract

Institutions are required by federal laws and regulations to oversee and evaluate their programs, facilities, and procedures for using animals in research, teaching, and/or testing activities. These responsibilities are specifically charged to an institutional official (IO) and an institutional animal care and use committee (IACUC). Initially, the individuals tasked with these responsibilities seldom have the requisite knowledge or experience to fulfill their charges effectively. Furthermore, simply reading the regulatory requirements does not prepare the novice IO and IACUC members to effectively monitor and guide the program. As a result, many new IOs and IACUC members are managing their responsibilities with insufficient understanding of the laws, regulations, standards, and policies. Specific training strategies for inexperienced IACUC members are needed to help them understand their responsibilities for ensuring animal welfare through an effective, high-quality, and compliant animal care and use program that supports the critical research needed to improve human and animal health. Likewise, most IOs would benefit from training to help them better understand their responsibility for enhancing or maintaining the quality of the institution’s animal care and use program. Education and training should begin with an orientation to the laws, regulations, standards, and policies. Continuing training and education are also important to keep abreast of the changes in the interpretation of these laws and regulations as well as the changes in veterinary science. For both the IO and the IACUC, understanding and acceptance of their authority and responsibilities are significant factors in establishing and maintaining a quality animal care and use program.

Key Words: continuing education; IACUC; institutional animal care and use committee; institutional official; requirements for training

IACUC Training

Overview

Is There a Need for IACUC Training?

Institutional animal care and use committees (IACUCs) are charged by federal law and regulations with overseeing and evaluating the institution’s animal program, facilities, and procedures (AWA 1990, Section 2143; CFR 2002, Subpart C, 2.3.1.a; PHS 2002) and for certifying compliance with federal requirements (CFR 2002, Part I, Definition of Terms). With perhaps the exception of members who are laboratory animal veterinarians by training, IACUC members come to the committee without knowledge of the rules, regulations, and expectations necessary to assess whether or not the institution’s program is in compliance. If committee members read all of the relevant regulations and documents (Table 1) and listen intently to more experienced members during meetings, program reviews, and facility inspections, they may eventually learn what they need to know. For many, however, that process may require too much time; it also may prove frustrating to new members trying to understand and fulfill their roles. Numerous US Department of Agriculture (USDA) inspections and Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) site visits...
Is There a Requirement for IACUC Training?

Some institutions have interpreted the statement from the 1966 Animal Welfare Act (AWA\(^1\)), “Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment . . . “ (AWA 1990, Section 2143), to imply at least an expectation, if not a requirement, for IACUC member training. Others have determined that Section 2.32, “Personnel qualifications,” issued by the USDA in 1989, implies such a requirement: “It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel” (CFR 2002, Subpart C, 2.32).

Following publication of the 1996 7th edition of the National Research Council Guide for the Care and Use of Laboratory Animals (NRC Guide\(^1\)), in which it is stated, “specific training to assist IACUC members in understanding and evaluating issues brought before the committee” should be provided (NRC 1996, p. 9), AAALAC International site visitors began asking accredited institutions to describe their training for committee members. The first revised edition of the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag Guide\(^1\)), published in 1999, further stated that the committee “should be composed of individuals who are qualified by experience or training to evaluate the programs . . .” (FASS 1999). Department of Defense (DOD\(^1\)) regulations require IACUC members and alternates at DOD facilities to receive initial training that consists of at least 4 hours of regulatory responsibilities and proper techniques of animal protocol review as well as an additional 4 hours of training on humane care and ethical issues dealing with animal use (DOD 2005). With the release of an updated animal research policy in May 2005, Department of Veterans Affairs (VA\(^1\)) IACUC members are required to pass an annual examination in the web-based course “Essentials for IACUC Members” at www.researchtraining.org (VA 2005). For many institutions, the major impetus to provide IACUC member training was the March 2006 revision of USDA Animal and Plant Health Inspection Service (APHIS\(^1\)) Animal Care Policy #15, IACUC Membership, which states: “The research facility is responsible for ensuring their qualification, and this responsibility is filled in part through the provision of training and instruction” (USDA 2006). As a result of this policy revision, USDA’s veterinary medical officers (VMOs\(^1\)) started citing institutions during the annual inspections for failure to provide training. This article addresses several ways to provide training for members of IACUCs.

Initial Training of New Committee Members

Initial training of scientific members can begin during the IACUC’s semiannual laboratory visits or through other forms of post approval monitoring. During these interactions, the IACUC has an opportunity to educate the scientists about the role of the committee, and to generate interest in serving as a scientific member, a membership position required by the Ag Guide, the NRC Guide, and PHS Policy (FASS 1999, p. 3; NRC 1996, p. 9; PHS 2002, IV.A.3.h.2).

Initial training also can occur during the selection process of new committee members. During the recruitment process, the “recruiter” should discuss IACUC responsibilities including the time commitment for attending meetings, reviewing the program and protocols, and inspecting facilities. An opportunity to attend IACUC meetings can help prospective members with their decision-making process. These approaches can be very effective training tools when a conscientious attempt is made to be realistic and matter-of-fact without overwhelming the recruit with information and concerns about the amount of work involved. Both approaches are especially effective in recruiting nonaffiliated and nonscientific (NA-NS\(^1\)) members. Consider providing potential NA-NS members a copy of the National

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\(^{1}\)Each year representatives of OLAW, APHIS, and AAALAC International mention and/or discuss commonly cited deficiencies.
Orientation of New IACUC Members

As mentioned above, the 1996 revision of the NRC Guide suggests states’ “institutions should provide orientation, background materials, and resources and, if necessary, specific training to assist IACUC members in understanding and evaluating issues brought before the committee” (NRC 1996, p. 9). A well-designed 2- to 3-hr orientation for new members should begin to reap rewards with the first meeting they attend if the new members know the purpose of the committee and scope of the IACUC’s responsibilities. New members who have been through an orientation session should come to the first meeting with a general understanding of expectations and possibly the corresponding workload. The goal of orientation should be to provide an overview and the necessary resource documents (see Table 1) to allow new members to be effective members within their first few months on the committee. An important outcome is for the new members to leave orientation with a sense of pride and awe at their responsibilities, as opposed to feeling overwhelmed and wondering how to resign quickly.

Overview of Requirements and Expectations for IACUC Members

Committee members should have a copy (paper or electronic) of all relevant publications in Table 1 and know how to access those in Table 2. In many institutions, all of the documents in Table 1 are relevant to IACUC members. If agricultural animals are used for food and fiber research or teaching, IACUC members should have a copy of the Ag Guide. IACUC members at DOD and VA facilities need to be equipped with their specific policy documents. For institutions receiving funds from PHS agencies, the IACUC members should be given the PHS Policy, the USDA regulations, and the NRC Guide. Some institutions are subject to USDA regulations only, whereas some unregulated institutions voluntarily follow the NRC Guide. AAALAC International-accredited institutions must be in compliance with the NRC Guide and all statutes and governmental regulations that bear upon animal care and use.

To facilitate assimilating this wealth of information, consider providing a cover memorandum that lists specific sections applicable to the IACUC. To ease new members into becoming familiar with the documents before their first meeting, encourage them to read the Introduction and Chapter 1 of the NRC Guide and the Ag Guide, if applicable, for a general overview of expectations for a quality animal care program. In addition, to be in compliance with the requirement that IACUC members be familiar with the intent of the AWA (USDA 2006), provide a copy of the two-page summary available at www.aphis.usda.gov/lpa/pubs/awact.html.

An overview of the expectations should include the roles of the following key members of the animal care and use program: the scientists, the attending veterinarian (AV\(^1\)), the IACUC coordinator or support staff (if applicable), the institutional official (IO\(^1\)), the animal husbandry and veterinary technical staff, the animal facility supervisor or manager, and the IACUC itself. It also is important to describe the role of the NA-NS members. At this time, it may be helpful to engage the members in a discussion of the philosophy of the IACUC as it relates to balancing its dual roles of protecting the welfare of animals and facilitating research and teaching using animals. In addition, it can be meaningful to have the AV and IO discuss their roles and responsibilities in the animal care program. (Information about expectations for these positions can be found in the section about training the IO below.) Following that sequence, a brief review of each of the basic functions of an

Table 2 Recommended readings\(^a\)

- “ARENA/OLAW\(^b\) Institutional Animal Care and Use Committee Guidebook,” 2nd ed., 2002
- “NASA Principles for the Ethical Care and Use of Animals.” National Aeronautics and Space Administration, March 1997
- “Report of the American College of Laboratory Animal Medicine on Adequate Veterinary Care in Research, Testing, and Teaching,” 1996
- “Report of the AVMA Panel on Euthanasia,” JAVMA 218(5), March 1, 2001 (et seq.)
- Institutional Administrator’s Manual for Laboratory Animal Care and Use, 1988, NIH Pub. No. 88-2959
- A comprehensive list of “Reference Resources” that each institution should have available is provided by AAALAC International at www.aaalac.org/accreditation/resources.cfm.

Note: Institutions should consider providing nonscientific members with a medical dictionary.


IACUC, as outlined in PHS Policy and USDA regulations (PHS 2002, IV.B.1-8; USDA 2006, 2.31.c.1-8), should suffice to convey a broad overview of expectations and facilitate understanding of the scope of the program.

To help new members feel more comfortable at their first meeting, allow time during orientation for discussion of the protocol form and process. Members should be given a written description of the review process for future reference (available in the institution’s PHS Assurance Statement or AAALAC International Program Description). This description is especially critical for NA-NS members. Generally, scientific members understand the process because they have submitted protocols, but NA-NS members are not likely to be familiar with this process. Scientific members should be cautioned, however, that in their role on the IACUC, the review principles are different from those for review of manuscripts and grants. IACUC members should approach protocol review as a collegial interaction or exchange of information in which the goal is improved animal welfare in the context of good science and/or teaching activities.

Additional documents to provide new members, but not necessarily to review during orientation unless time allows, include a list of all committee members and IACUC staff with contact information, dates of all meetings and inspections, written instructions on accessing the secure website (if applicable), the PHS Assurance, AAALAC International Program Description, and copies of all IACUC policies and guidelines. Committee members can manage these items, as well as the protocol review form and description of process mentioned above, if the material is contained in a three-ring binder with a table of contents and corresponding tabs. Alternatively, a well-designed IACUC website will allow members online access to this wealth of information 24 hours/day, as long as they have access to a computer.

A beneficial conclusion to an orientation is a tour of some (or all, time permitting) of the animal facilities. The tour gives the AV and/or facility manager(s) an opportunity to educate IACUC members outside the more formal, regulatory-required, semiannual inspections.

Some institutions accomplish the objectives of orientation in ways that are less formal than described above. In some facilities, the chairperson meets with the new member(s) and reviews regulations, documents, and responsibilities. In other facilities, the chairperson, AV, and IACUC coordinator jointly meet with new members, whereas in others, the AV and/or facility manager conduct the informal orientation.

The take-home messages from orientation, regardless of the approach, should include the following: The IACUC is responsible for oversight, assessment, and evaluation of the institution’s animal care and use program; every member has an important role to play; and protocol review is not the sole activity of the IACUC.

We offer the following closing words of caution: Those who design orientation programs are advised to remember that adults learn differently from children and differently from each other. The topic of adult learning strategies has been thoroughly reviewed in one of the previous articles in this issue (Dobrovolny et al. 2007). In designing an IACUC orientation, consider including a mix of web-based modules (see below), PowerPoint presentations, handouts, and homework assignments (Kennedy 2006). Above all, remember: Do not overwhelm new members at orientation; you want them to come back.

**Continuing Education for IACUC Members**

The following quotation accurately describes the need for continuing education:

“Laboratory animal science is a dynamic field. New animal models are continually developed, new drugs are introduced and new scientific procedures are implemented. So no matter what form your IACUC training takes, it’s important to develop a long-term strategy for continuing education to help committees stay current with changes in science and regulations” (AAALAC 2002, p. 11).

**What Kind of Continuing Education Is Important?**

**Laws and regulations.** Why is it important for IACUC members to participate in ongoing training and education? While there have not been major changes in federal legislation regarding the use of animals in research, teaching, and testing, there have been updates from USDA regarding interpretations of regulations and from the Office of Laboratory Animal Welfare (OLAW) in the form of written guidance. Examples include the 2006 guidance from OLAW on the use of telecommunications for IACUC meetings, a compilation of Disaster Planning and Response Resources, revision of the USDA APHIS Animal Care’s Research Manual for Inspectors (located on the APHIS website) that outlines expectations of the USDA inspectors when they conduct facility inspections, and revisions to Policy 15 (IACUC Membership). It is important to keep IACUC members abreast of these changing standards and policies.

**Professional standards.** As stated above, laboratory animal science is a dynamic field. Refinements in the care and use of animals in research, teaching, and testing are ongoing. Scientific research, by its nature, is constantly changing and evolving. Professional societies address these changes and refinements by publishing updated guidelines and position statements. For example, the APS recently published guidelines for using animals in exercise studies (www.the-aps.org/pa/action/exercise/). Another new resource on enrichment for nonhuman primates developed in concert with the Association of Primate Veterinarians, American Society of Primatologists, and USDA Animal Care was announced by OLAW in May 2006. In order for the IACUC to keep pace with current accepted practices,
committee members must be given new information and have an opportunity to discuss and apply it to their animal care and use program.

Institutional policies and guidelines. The periodic review of institutional policies and procedures pertaining to the animal care and use program is essential as new animal species, models, and/or procedures are introduced at your institution. An ideal time to review these policies and obtain input from the scientists is during the semiannual facility inspection and program review process. By talking with scientists and their staff, IACUC members may identify the need for new policies or guidelines that would address a particular question or problem. In addition, as with the implementation of protocol activities, there can be some drift or lack of institutional memory about current policies and procedures within the organization and the appropriate adjustments can then be made. Some policies may simply be outdated or no longer needed due to changes in the scope of the animal use program.

Refresher training and reinforcement of essential IACUC roles and responsibilities. Some IACUC members may not grasp the multiple essential roles the IACUC serves for both the institution and the research staff. The US concept of research regulation is heavily based on a philosophy of peer-based self-regulation at the institutional level. An independent, well-trained, and fully engaged IACUC is critical to the success of this philosophy. When functioning properly, the IACUC provides an institutional shield for research staff against unfair allegations and criticism directed at them internally or externally when they are conducting work approved by the IACUC. It also plays a critical role in maintaining public confidence in the institution’s general commitment to a high-quality animal care and use program, and in meeting the specific public expectation that animals will be treated humanely as they contribute to advances in human (as well as veterinary) medicine and health. Thus, an important part of IACUC training is helping members understand their role and responsibilities in a context much larger than just compliance.

Ongoing training can serve to reinforce and help IACUC members better understand their responsibilities. Refresher training regarding federal mandates can be used to strengthen the committee’s effectiveness and may result in changes that make the process work more smoothly. For example, a review of the protocol application form can be very useful to assess whether it addresses all of the requirements of the AWA and the PHS Policy. In addition, consider whether questions are stated to elicit the appropriate responses regarding the care and proposed use of animals. This exercise raises the IACUC’s awareness as to why the question is being asked and how it can be better worded.

How Is Continuing Education Best Provided?

One of the challenges for an IACUC (or an IACUC administrator) is to incorporate ongoing continuing education without imposing additional burden on committee members. There is usually so much time invested in routine IACUC duties such as protocol review, facility inspections, and program review that it is difficult to set aside additional time for ongoing training. Committee members need to be able to see the benefits of ongoing training as helping them save time by communicating more effectively and performing their functions more efficiently.

One of the benefits of continuing education and self-assessment is to stimulate changes in knowledge, attitudes, and behaviors that will ensure the humane care of animals (NRC 1991) and facilitate research more effectively and efficiently. By providing a forum for exchanging ideas and expressing concerns, we can understand better when and how to apply the information obtained through the various sources.

There are many different ways to provide ongoing training. Key factors include the size and type of the institution and the scope of the animal use program. The available time and financial resources also dictate the way continuing education is conducted. Other important factors are current compliance issues and committee concerns.

An informal survey of IACUC members and administrators was conducted on the IACUC-Admin@list.msu.edu listserv in 2006. The responses from representatives of 18 different institutions shared both common and innovative ways to provide continuing education for IACUC members. One institution has obtained grant funding to provide online training specific to conducting facility inspections. At another institution, the IACUC plays Team Trivia. The respondent wrote, “My husband writes software and I had him create a team trivia program that can be used for review or to quiz IACUC members on any topic. It looks like Jeopardy and the IACUC loves it! I customize the topics, questions, and answers for each meeting” (Beran 2006).

The most common methods of ongoing training were reported in the following order of descending frequency:

1. Resources to attend workshops and conferences: Training programs such as IACUC 101 and the PRIM&R and SCAW conferences as well as other external training programs described below serve as excellent training activities. This approach is especially helpful for non-affiliated members because it allows them to network with each other and ask questions that they may be hesitant to raise at their home institution.
2. Mini-continuing education opportunities during scheduled IACUC meetings: Responses ranged from using the IACUC meeting to discuss scenarios, particularly from Lab Animal or IACUC 101, to the review of an article, or discussion of a relevant topic.
3. Timely, interesting, and concise reports from IACUC members or staff who have attended relevant workshops or conferences: By including continuing education as a standing agenda item, it stays on the radar screen.
4. The IACUC meeting itself: The meeting can be used to
introduce and train a prospective or new member by partnering that person with a more experienced member who serves as a mentor. Using the committee functions such as facility inspections and post approval monitoring of protocol activities can also provide ongoing training. Serving on subcommittees with a specific topic to address is another way to learn about an IACUC issue in more depth and to apply it to a specific policy.

5. Distribution of relevant articles, newsletters, and information before or at the meeting: This approach is most effective if discussed at the convened meeting.

6. Internet resources: This approach was utilized by a majority of the respondents for ongoing training. The two most cited on-line training resources were subscribing IACUC members to the AAALAS Learning Library and using www.ResearchTraining.org as a refresher course.

7. Guest speakers and consultants: Topics such as research ethics, AAALAC International issues, and enrichment programs were mentioned.

8. Retreats that focus on key IACUC issues without interruptions from the daily routines: If planned well in advance and delivered off site, or at least away from email and phones, this approach can be an effective way to provide a quality educational experience.

9. Consultation and ongoing one-on-one guidance to individual members by the chairperson, vice chairperson, AV, and IACUC administrator to respond to specific questions and to provide clarification of issues as they arise.

Using Regulatory and Accreditation Reviews as Training Opportunities

Preparing for and participating in an AAALAC International site visit are excellent opportunities for the continuing education of IACUC members. Preparation of the program description requires a careful examination of all aspects of the animal care and use program. IACUC members can serve on subcommittees with veterinary and IACUC staff in the development of this document. It can also be very beneficial to include them in the site visit from the opening remarks and program review, the facility walk-through, and the exit briefing. This inclusion is especially important for the NA-NS members because it gives them a greater understanding of the process and an excellent opportunity to learn from these highly qualified individuals. For all members, participation in the program review discussion with the AAALAC International site visitors and the facility tour are excellent ways to expand their knowledge about the current guidelines and practices for maintaining a high-level program.

It is more difficult, but possible, to have IACUC members participate in USDA inspections due to the unannounced aspect of these visits. When IACUC members are available to participate in the inspection, however, the result is a valuable learning experience. It is helpful when IACUC members have some preparation such as having a general knowledge of the USDA APHIS Animal Research Manual so that they know what to expect. Some VMOs are willing to meet with local IACUCs to review the responsibilities of the VMO during inspections, providing yet another excellent training opportunity for the IACUC.

An OLAW site visit is another opportunity for IACUC members to participate and learn more about the PHS Policy and OLAW’s expectations of the IACUC. These visits are generally announced in advance, and institutions may be selected at random or “for cause.” Random visits are to monitor the self-regulation process by ensuring that an institution is in compliance with its PHS Assurance. The for cause visits focus on specific issues with follow-up as necessary.

Online Training and Informational Resources

Many IACUCs rely on online training opportunities for both training and information resources. These resources abound. Those most frequently cited and recommended as adjuncts to the training opportunities described above are highlighted in Table 3. A very lengthy and detailed list of relevant Internet resources can be found in the June 2006 issue of Lab Animal (DenHouter and Hankenson 2006).

External Training Programs

Multiple venues for IACUC training opportunities exist outside the institution. These programs are available through state and regional associations and federal agencies as well as major biomedical research associations and organizations. A representative sample follows.

Programs Offered by International and National Organizations

American Association for Laboratory Animal Science (AAALAS1). The AALAS National Meeting offers a focus on IACUC training within the session track “Animal Welfare, Regulatory Compliance, and Public Education.” IACUC topics are addressed in poster sessions, seminars, special topic lectures, workshops, and roundtable discussions. Information is available at www.iacuc.org.

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International1). Topical education services are provided by AAALAC International in the form of in-house training sessions. This program is intended to help institutions “pro-actively manage animal care and use issues in ways that meet AAALAC International standards.” The program consists of several modules, all under the heading of “AAALAC International’s Expectations for Animal Care and Use Committees” and presented over a period of 6.5 hours. Information is available at www.aaalac.org.

Canadian Council on Animal Care (CCAC1). CCAC is the national body that oversees the care and use of animals in science through its peer-based Assessment, Guide-
Table 3 Free online training resources

- Tutorial on the PHS Policy on Humane Care and Use of Laboratory Animals at //grants.nih.gov/grants/olaw/tutorial/index.htm includes links to relevant standards, regulations, and guides as well as other educational and training sites useful in maintaining compliance with the PHS Policy.
- The Medical Research Service in the VA Office of Research and Development provides very useful tutorials for VA and non-VA IACUC members. Each module includes an exam and printable version of a certificate of completion (available at www.ResearchTraining.org).
- The AALAS Learning Library (www.aalaslearninglibrary.org) incorporates all of the ResearchTraining.Org courses along with other courses in regulations, biomethodologies, occupational health and safety, pain and distress management, animal husbandry, and facility management.
- Developed as an organizing tool, www.IACUC.org is an information resource for members and staff of institutional animal care and use committees. Listserv and Information Exchange Forums
- COMPMED (www.aalas.org/association/links/compmed.htm), the AALAS Comparative Medicine Discussion List, is a restricted listserv for discussing the topics of comparative and laboratory animal medicine. Matters of specific interest to IACUCs are included in the range of laboratory animal science and medicine topics.
- IACUC-FORUM is a listserv in which IACUC members and staff may discuss issues relating to laboratory animal research in a closed forum. Because subscription is restricted to AALAS Institutional Member organizations, the Institutional Contact coordinates subscriptions for each institution’s IACUC members and staff.
- IACUC-Admin (IACUC-Admin@list.msu.edu), a relatively new service hosted by Michigan State University, is open to IACUC members and staff interested in an information exchange and joint problem-solving related to IACUC issues, activities, and management.
- The OLAW Listserv (/grants2.nih.gov/grants/olaw/references/list.htm) is used by OLAW for posting announcements, guidance, publications, and upcoming education programs and conferences related to implementing the PHS Policy as well as new information posted to the OLAW listserv. It is not a discussion list and is available to all interested individuals.
- SCAW’s “IACUC TALK” (www.scaw.com) is a forum for IACUC members to consider protocol, research animal welfare, and other issues. It is not in a mailing-list format but in a forum in which comments and questions are posted. Subscriptions are free and open to everyone.

*bAALAS, American Association for Laboratory Animal Science; IACUC, institutional animal care and use committee; OLAW, Office of Laboratory Animal Welfare; PHS, Public Health Service; SCAW, Scientists Center for Animal Welfare; VA, Veterans Affairs.

tables, and Education programs. Educational materials of interest to animal care committees (ACCs) are made available through the CCAC website and include 12 web-based modules that cover the general core topics for all animal users and specific core topics (www.ccac.ca/en/CCAC_Programs/ETCC/Intro-coretopics-Web11.htm). CCAC also conducts annual meetings with ACC members during the CCAC National Workshop and jointly with the Canadian Association for Laboratory Animal Science (CALAS) Annual Symposium (ACC-101 and scientific sessions) as well as with ACCs during CCAC assessment visits. CCAC also offers specialized training to individual ACC members by inviting them to participate on CCAC assessment panels. Information is available at www.ccac.ca.

Public Responsibility in Medicine and Research (PRIM&R). PRIM&R is a national organization dedicated to creating, implementing, and advancing the highest ethical standards in the conduct of research. On an annual basis, PRIM&R presents a day of preconference programs followed by a 2-day annual IACUC conference that alternates between Boston and San Diego. Preconference offerings include three distinct all-day specialized programs of interest to IACUCs and affiliates and/or biosafety personnel. The 2-day conference includes but is not limited to special topics lectures, plenary sessions, multiple workshops, and roundtable discussions. Information is available at www.primr.org, or e-mail info@primr.org.

Scientists Center for Animal Welfare (SCAW). SCAW advances the responsible use of research animals in a variety of venues including annual conferences, workshops, and publications, all of which cover topics of interest to IACUCs. In addition, SCAW offers IACUC-Advanced for more seasoned IACUC members. This 1-day workshop facilitates group discussions about specific, complex topics relevant to IACUC functions and best practices. While each workshop offers a similar format, the particular agenda is customized both to meet the needs of the hosting institution and to address any new and timely issues. Information is available at www.scaw.com, or e-mail info@scaw.com.

Programs Offered by Government Agencies

Animal Welfare Information Center (AWIC). A 1½-day workshop, “Meeting the Information Requirements
of the Animal Welfare Act,” is offered several times throughout the year by AWIC via the USDA National Agricultural Library (NAL). The workshop focuses on the AWA, the concept of the 3Rs (refinement, replacement, reduction; Russell and Burch 1959), the regulatory requirements for conducting animal alternatives searches, literature resource services including NAL AWIC, and instruction for seeking alternatives information using various literature databases and networks. Information is available at www.usda.gov/awic and www.nal.usda.gov/awic/awicworkshops/regform.htm, or e-mail awic@nal.usda.gov.

IACUC 101 series. Cosponsored by OLAW and PHS-assured institutions, state biomedical research associations, and/or national organizations, the IACUC 101 series consists of didactic and interactive training programs designed to provide information on the role and responsibilities of IACUCs, including an understanding of federal policies and regulations governing laboratory animal welfare. The 1- or 2-day programs are offered across the country approximately six times a year. The course features a didactic comprehensive overview of laws, regulations, and policies supplemented with examples and approaches for successful and effective implementation and administration, followed by an opportunity to participate in deliberative and challenging mock IACUC sessions. The IACUC 101 program focuses on the basics, while the supplemental IACUC 101 PLUS, 201, and 201 PLUS programs focus on processes and include several highly interactive breakout sessions. The ability to meet and talk to faculty and network with other IACUC 101 series participants is also a valuable component of the course. Information is available at grants.nih.gov/grants/olaw/iacuc101s.htm, or e-mail mljames@socket.net.

Programs Offered by State Biomedical Research Associations

States United for Biomedical Research (SUBR). Membership societies of SUBR, a national network of nonprofit associations to promote health through science and education, are also involved in IACUC training. These associations offer their own unique regional programs and/or conduct programs in conjunction with each other or other national organizations listed above. Information is available at www.statesforbiomed.org. The following descriptions are a sampling of the programs offered by these organizations.

California Biomedical Research Association (CBRA). CBRA offers two professional education conferences each year in the western region. Specialized and timely topics include ethics and emotions related to research with animals, or animal activism and crisis readiness, and regulatory and compliance topics that train and inform the biomedical research community. Topics include IACUC 101; IACUC Rights, Roles & Responsibilities: Post Approval Compliance; IACUCs and Security; Compliance: The Right Stuff; and Occupational Health and Safety: A Continuing Challenge for Biomedical Research. CBRA alternates its conferences between northern and southern California and plans to offer programs in alternate years in the western region outside California. Information is available at www.ca-biomed.org, or email info@ca-biomed.org.

Massachusetts Society for Medical Research (MSMR). MSMR offers a continuously updated series of 1- to 2-day professional development workshops that are focused on timely and relevant IACUC themes such IACUC training, IACUC ethics, post approval compliance monitoring, and harmonizing IACUCs, institutional biosafety committees, and institutional review boards. Some MSMR programs travel outside Massachusetts to California and Ohio. Information is available at www.msmr.org, or e-mail contact@msmr.org.

Michigan Society for Medical Research (MISMR). MISMR annually offers a regional 1-day seminar that focuses on providing guidance for developing and maintaining strong and effective animal care and use programs. The seminar features multidisciplinary presentations geared to the needs of IACUC members and staff. Information is available at www.mismr.org, or e-mail mismr@umich.edu.

New Jersey Association for Biomedical Research (NJABR). NJABR, the first state biomedical research association to offer IACUC training, presents an annual 1-day seminar, “IACUC: The Charge & The Challenge.” This program consists of several sets of workshops during which multiple topics are addressed. Attendees receive hardcopies and/or a compact disc of presentations, laws and regulations, resource documents, and other timely and relevant materials. Information is available at www.njabr.org, or e-mail info@njabr.org.

Northwest Association for Biomedical Research (NWABR). NWABR presents annual 1 1⁄2-day IACUC Regional Education Conferences in Seattle, Washington, with topics that challenge IACUCs. The program typically consists of a mix of general sessions, interactive breakouts, and networking opportunities including those with OLAW, AAALAC International, and USDA representatives. Information is available at www.nwabr.org, or e-mail info@nwabr.org.

Ohio Scientific Education & Research Association (OSERA). OSERA offers a 1-day in-house training program for IACUCs primarily in the state of Ohio. Program topics can be customized based on institutional needs but generally address laws, regulations, and policies; IACUC responsibilities; semiannual reviews and inspections; and protocol review. Information is available at www.osera.org.

Summary

“Effective IACUC training can take many forms, but the main goal is to initiate and implement a system that develops appropriate levels of knowledge and expertise that results in a well-functioning committee” (AAALAC 2002, p. 11). The results from an AAALAC International site visit, the USDA inspection reports, the 6-month program review, and other reviews of the program are all measures of the success of the training program.
We believe that the best approach is to use a variety of training venues to accommodate members. Assessing the effectiveness of ongoing training activities can be accomplished by asking IACUC members and the IO if their needs are being met and if the IACUC is functioning effectively. Often the best training occurs when the committee recognizes a need and realizes that taking the time to address it will be beneficial. It is also important to receive input from the principal investigators regarding their issues and concerns. For instance, it is important to question whether the policies are relevant, and whether the protocol form is clear and helpful. Of course, external assessment of the animal care and use program is the final test.

**Training the IO**

More important than knowing all of the regulations that govern the care and use of animals in research, teaching, and testing, the IO should be aware of the regulations, recognize and support the key players in the program, and know where to find more information when the need to know arises. The goal of “training” the IO is to increase awareness, impart a broad overview of the program, and provide key reference documents. The IO establishes and maintains the culture of the animal care and use program. The IO should understand the importance to the institution of full cooperation and compliance by all, and the consequences of noncompliance.

The first opportunity to “train” the IO may occur while helping the institutional leadership to identify the appropriate individual to serve as the IO. Neither the USDA nor the OLAW definitions (Table 4) state emphatically that the IO must be the president or the chief executive officer (CEO) of the institution, although the responsibility generally defaults to the most senior management representative. For USDA purposes, the IO must be someone who can legally commit the institution to be in compliance (CFR 2002, Part 1, Definition of Terms). For the PHS, the IO must be someone who has the administrative and operational authority to commit institutional resources to help assure compliance (PHS 2002, Section III, Definitions).

It is optimal for the IO to be a recognized and respected institutional authority whose opinions and abilities are trusted. The IO should commit to a quality program and set the standard of excellence. While some institutions designate multiple IOs (e.g., one IO for the animal program, another IO for the human subjects research, and another IO for compliance in general), other institutions designate one individual to be IO for all three programs. The IO should define and assign responsibilities for the animal care and use program within the organization to ensure that the institution meets its responsibilities for developing and administering these programs.

If the CEO or president of the institution plans to delegate the responsibilities of the IO, the next training opportunity occurs during the preparation of the appointment letter because such delegation of responsibilities must be in writing (PHS 2002, footnote 5). Other training opportunities exist in conjunction with submission of an AAALAC International Program Description, PHS Assurance Statement, or the USDA Annual Report as well as during preparation for an AAALAC International site visit or after a USDA inspection. Because both the AV and the IACUC serve in advisory roles to the IO, they should fully understand the responsibilities of the IO and often are in the best position to train this individual.

**What Does the IO Need to Know?**

As a cautionary note, there is a fine line between informing IOs of their responsibilities and overwhelming them with information. Training should begin by providing him or her with a general overview of his/her responsibilities and then providing more detailed information over time. This information should be sufficient in both quality and quantity to enable the IO to understand the complexities and the requirements of the program and to assess whether the AV and the IACUC are fulfilling their responsibilities.

The IO should be familiar with the regulatory documents identified in Table 1. To facilitate his or her assimilation of this wealth of information, consider providing a cover memo that accurately reflects the information provided in the following resources:

**PHS Policy on Humane Care and Use of Laboratory Animals:** To receive funds from any PHS agency (such as the NIH), the institution must be in compliance with the

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**Table 4 Definitions of “institutional official”**

| USDA: | “Institutional official means the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR parts 1, 2, and 3 will be met.” |
| OLAW: | “An individual who signs, or has the authority to sign the institution’s Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.” |
| | “For purposes of the PHS Policy, the IO is that person in the organization having the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with requirements of the PHS Policy.” |

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PHS Policy on Humane Care and Use of Laboratory Animals. A list of PHS agencies can be found in the definitions section of this document; a list of the requirements for the IACUC can be found in IV.B on page 11. CFR Parts 1, 2, and 3: To use animals in research and teaching, the institution must be registered with USDA and must be in compliance with the Standards and Regulations found in 9 CFR Parts 1, 2, and 3. See section 2.31 for the requirements for the committee and Sections 2.33 and 2.40 for expectations of the AV.

NRC Guide: The Introduction and Chapter 1 of the NRC Guide provide an overview of expectations of a program. An institution accredited by AAALAC International must be in compliance with the NRC Guide. If agricultural animals are used for teaching and research in agriculture, the institution should comply with the Ag Guide, which is modeled on the NRC Guide. A good overview of expectations for an agriculture program is provided in the Introduction and Chapter 1.

The two-page “Quick Reference to the Responsibilities and Functions of the Institutional Official (IO) for Research Facilities under the Animal Welfare Act,” available at www.nal.usda.gov/awic/legislat/awabrief.htm, is another good resource. The quick reference guide used in IACUC 101, “IACUC and Institutional Requirements,” may also be useful.

Finally, the IO should understand that a successful program includes four basic components in which specific responsibilities are assigned to the (1) institution, (2) the IACUC, (3) the AV, and (4) the scientists.

Requirements for the Institution

The IO is primarily responsible for ensuring that the institution provides a functioning IACUC, veterinary medical care, an occupational health and safety program, personnel training, and disaster, emergency, and/or crisis plans. The IACUC is responsible for evaluating those programs. However, because it is the IO who signs the annual reports to OLAW and the USDA, it is critical that IOs understand the information that is being conveyed.

The PHS Assurance, the primary document that describes the institution’s program, is signed by the IO and submitted to OLAW. The IO must understand the extent of this commitment when he or she signs the Assurance Statement, as explained by OLAW:

“OLAW approval of the Assurance Statement commits the institution, its officials, committees, investigators, and any of its agents to full compliance with provisions of the PHS Policy, including the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, the Guide for the Care and Use of Laboratory Animals, and, as applicable, the Animal Welfare Act (AWA) Regulations and other federal statutes and regulations applying to animals” (available online: www.labanimal.com/iacuc/potkay0500.htm).

Additional information regarding requirements for the facility can be found in both the NRC Guide and the Ag Guide as well as in the USDA regulations Subpart C, 2.33(b)(1) and Part 3, Standards.

Specific IO Responsibilities

Suspensions and serious or continuing noncompliance. If the IACUC suspends an activity, the IACUC, in consultation with the IO, must report the suspension to OLAW and USDA (for regulated species) and AAALAC International, if applicable. Furthermore, “By signing the Assurance, the Institutional Official (IO) also commits the institution to report promptly—along with corrective actions taken—any serious or continuing noncompliance with the Policy, any serious deviation from provisions of the Guide, and any suspension of an activity by the . . . IACUC” (www.labanimal.com/iacuc/potkay0500.htm).

Significant deficiencies. “A significant deficiency is one which . . . in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals” (CFR 2002, 2.31(c); PHS 2002, IV.B.4). Discussions of such problems by necessity should include consultation with the IO. The IO is also responsible for ensuring the correction of any deficiencies at the institution that have been identified by the IACUC during their semiannual inspections. Although this responsibility is not specifically mentioned in the Animal Welfare regulations, it is clearly implied.

Supporting decisions of the IACUC. “Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC” (CFR 2002, 2.31(d); PHS 2002, IV.C.7). For example, if an IACUC approves a proposal to use animals, the institution can decide not to allow the project to move forward. The converse is not true, however. If the IACUC disapproves a project or activity, the institution cannot override the IACUC’s decision and allow the project to be conducted.

Organizational structure. It has been OLAW’s experience that it is usually best when the AV and the IACUC report separately and directly to the IO rather than having the committee report through the AV to the IO (ILAR 1993). Many IOs also have a professional IACUC staff reporting directly to them. This arrangement provides additional checks and balances, and allows the IO to obtain different perspectives about the same program, which should help the IO assess the quality of the program.

Requirements for the IACUC. The IO should know that the IACUC is required to review the program, all activities involving animals, and concerns involving the care and use of animals, as well as to make recommendations to the IO and suspend activities if necessary.
Training the IO about the committee responsibilities may  
best be provided by IACUC members themselves. An  
excellent way to conduct this training is to use either the  
PHS Assurance or AAALAC International Program De-  
scription. Carefully review the document with the IO; do not  
simply give the 100-page document to the IO and expect it  
to be read and understood. For example, the IO should be  
informed that “We are required to do a semiannual review  
of programs: we do ours in February and August. We are  
required to report the results to you; you can expect a report  
from us in April and October. We are expected to review  
concerns: we have a poster in every laboratory in the insti-
tution that tells people how to report concerns.” This ap-
proach also will give the IO an opportunity to determine  
whether the committee understands its responsibilities. See  
“Quick Reference to the Responsibilities and Functions of the  
Institutional Animal Care and Use Committee (IACUC)  

Requirements for the AV. The many responsibilities  
of the AV are succinctly catalogued in two documents: (1)  
the American College of Laboratory Animal Medicine  
(ACLAM) document on “Adequate Veterinary Care”  
(available at www.aclam.org/pub_adequate_care.html)  
(ACLAM 1996), and (2) “A Quick Reference to the Re-
sponsibilities and Functions of the AV for Research Facili-
ties under the Animal Welfare Act” (available at  
www.nal.usda.gov/awic/legislat/awabrief.htm). The opti-
mal “training” related to the responsibilities of the AV can  
be delivered via a tour of the facility during which the AV  
discusses various aspects of his or her responsibilities. At a  
minimum, the AV should meet with the IO to discuss an  
annotated copy of the USDA regulations at Subpart C, 2.33  
and Subpart D, 2.40. This tour should also incorporate ad-
ditional information as found in the NRC Guide and the Ag  
Guide.

Requirements for the scientists. While the regula-
tions do not specifically address responsibilities for princi-
pal investigators, the Animal Welfare Information Center  
(AWIC) published “A Quick Reference to the Responsibili-
ties and Functions of the Principal Investigator (PI) for Re-
search Facilities under the Animal Welfare Act” (available  
at www.nal.usda.gov/awic/legislat/awabrief.htm), which  
summarizes expectations. In 2006, OLAW published “What  
Investigators Need to Know About the Use of Animals”  
(NIH Publication No. 06-6009 (available at grants.nih.gov/  
grants/olaw/investigatorsNeed2Know.pdf), for general dis-
tribution to PHS-funded investigators. In general, the  
scientist and research staff should accept responsibility for  
the privilege of using animals in research, education, and  
testing activities; plan and conduct studies in the context of  
quality animal care; cooperate in the program; understand  
the role of the IACUC, perhaps serving on the committee at  
some time; be aware of the regulations that pertain to them;  
and participate in the training and occupational health and  
safety program.

Continuing education for the IO. The periodic ap-
ppearance of the IO at the beginning of an IACUC meeting  
is another useful approach to training for both the IO and the  
IACUC, not only to show support of the IACUC and rec-
ognition of its value but also to reiterate the IO’s role in the  
process of ensuring institutional compliance. Furthermore,  
this periodic face-to-face meeting with the IO provides  
IACUC members with the opportunity to share their perspec-
tive on the importance of communicating with the IO  
and their expectations for action when recommendations are  
made.

In many institutions, most training of IOs occurs  
through routine informal and unstructured interactions with  
the IACUC chairperson, the administrator, and the AV. The  
presence of the IO at the AAALAC International exit inter-
view can be extremely enlightening and should be encour-
aged, along with IO attendance at national meetings such as  
the annual PRIM&R and/or SCAW conferences.

Obtaining the IO’s signature on an annual USDA or  
PHS report and the submission of the semiannual reports  
also are opportunities for the IACUC to provide continuing  
education to the IO. When the IO’s signature is required, a  
meeting of the IACUC chairperson, AV, IACUC adminis-
trator, and IO to discuss the report is an excellent opportu-
nity to inform and update the IO regarding regulatory  
policies and expectations.

Summary

The IO legally commits the institution to compliance when  
signing the PHS Assurance Statement and USDA registra-
tion. It is therefore imperative for the IO to understand and  
respect the rules and regulations, and to support and rein-
force IACUC activities. To this end, the IO should be re-
ceptive to either formal or informal training in addition to  
continuing education, and the IACUC should take advan-
tage of numerous opportunities to provide this training.

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