**How to Work With Your Institutional Animal Care and Use Committee (IACUC)**

Richard E. Fish, PhD, DVM  
*Director, University Animal Resources; Associate Professor of Clinical Sciences, College of Veterinary Medicine,  
North Carolina State University*

**Introduction**

An institutional animal care and use committee (IACUC) is required by federal regulations for most institutions that use animals in research, teaching, and testing. The IACUC has a key oversight role, including the review and approval of animal use activities, and inspection of animal facilities. The principal investigator (PI) or instructor, and their staff, are responsible for understanding and following the regulations, as well as institutional policies, governing animal care and use. The objectives of this module are to help researchers:

* understand the laws, regulations, guidelines, and standards, as a basis for what the IACUC does;
* appreciate their responsibilities in the compliance process;
* communicate effectively with the IACUC.

The main body of this module provides basic information for both PIs and technical staff who are new to the process. Links within the module and additional resources at the end provide more thorough understanding of why IACUCs do what they do, including resources for training the IACUC member.

**The Rules**

Many institutions have for some time utilized committees to assist in the oversight of the animal care and use program. However, in the U.S., it wasn’t until 1985 that two laws at the national level were passed requiring an IACUC. These laws were the Health Research Extension Act (HREA) and key amendments to the Animal Welfare Act (AWA). Both laws led to statutory requirements for the composition and responsibilities of the IACUC.

Laws provide broad directives, including designation of a responsible federal agency; agencies in turn are responsible for creation of the regulations and associated policies. For the AWA, responsibility lies with the [US Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care](http://www.aphis.usda.gov/ac/); the rules promulgated by USDA Animal Care are commonly referred to as the [AWA regulations (AWARs)](http://www.aphis.usda.gov/ac/publications.html). In the case of the HREA, responsibility lies with the Office of Laboratory Animal Welfare (OLAW) in the Department of Health and Human Services, and the rules are articulated in the [“Public Health Service Policy for the Humane Care and Use of Laboratory Animals” (PHS Policy)](http://grants1.nih.gov/grants/olaw/references/phspol.htm).

Although many details of the two sets of regulations are similar, especially with respect to the IACUC (see sidebar), there are differences. The AWA covers (almost) all research facilities, but applies only to “animals,” as defined. This definition specifically excludes laboratory rats and mice, birds, and livestock species used in agricultural research. The PHS Policy covers all vertebrates, but applies only to projects funded by PHS agencies such as the National Institutes of Health, the Food and Drug Administration, and the Centers for Disease Control. These differences, as well as the fact that some institutions using animals are not covered by either set of regulations, mean that the institution itself must set policy about the roles and responsibilities of an IACUC. Many, if not most, institutions have judged that a coherent policy requires applicability to all animals regardless of funding source.

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| **Federally-Mandated Functions of the IACUC**   * Review at least once every six months the institution's program for humane care and use of animals. * Inspect at least once every six months all of the institution's animal facilities. * Prepare reports of the IACUC evaluations and submit the reports to the Institutional Official. The reports must distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. * Review concerns involving the care and use of animals at the institution. * Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training. * Review and approve, require modifications in (to secure approval) or withhold approval of activities related to the care and use of animals. * Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities. * Be authorized to suspend an activity involving animals. |

The federal regulations differ slightly in the requirements for the composition of the IACUC (see sidebar). However, the institution must decide how many committee members to appoint (above the minimum requirement), and make a variety of other decisions on matters not specified by the regulations. These include:

* frequency of meetings;
* specifics of paperwork, e.g., the “protocol form;”
* details of how the IACUC will conduct the review of animal use activities (protocols), e.g., designated vs. convened committee review, and how to handle “continuing review;”
* details of how the IACUC will conduct semiannual evaluations, i.e., facilities inspections and program review.

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| **Comparison of IACUC Composition Requirements**  From the PHS Policy:  The committee shall consist of not less than five members, and shall include at least:   * one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution; * one practicing scientist experienced in research involving animals; * one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and * one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.   From the AWARs:  The Committee shall be composed of a Chairman and at least two additional members; of the members of the Committee:   * At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility; * At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals. |

IACUCs use a variety of standards documents and guidelines to assist in their evaluation of animal care and use. Key among these are the [U.S. Government Principles for the Utilization and Care of Animals Used in Research, Teaching and Testing](http://grants1.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples). These principles articulate for all government agencies ethical standards for how animals should be treated. One of these principles refers to appropriate euthanasia of laboratory animals; specific guidelines for euthanasia methods are in the [Report of the American Veterinary Medical Association Panel on Euthanasia](http://www.avma.org/resources/euthanasia.pdf).

The [AWARs](http://www.aphis.usda.gov/ac/publications.html) include detailed husbandry standards that must be followed for the species covered. The PHS Policy refers to the AWARs, but also specifically to the [*Guide for the Care and Use of Laboratory Animals*](http://books.nap.edu/books/0309053773/html/index.html), a publication of the [Institute for Laboratory Animal Research](http://dels.nas.edu/ilar/). Another important publication is the [*Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*](http://www.fass.org/publications.asp), published by the [Federation of Animal Science Societies](http://www.fass.org/). This document does not have a direct regulatory connection, but is widely used by institutions, and AAALAC (below), in evaluating animal care and use programs in the agricultural setting.

In addition to procedural decisions, many institutions have judged it important to demonstrate a higher level of accountability by voluntarily participating in accreditation by the[Association for the Assessment and Accreditation of Laboratory Animal Care – International (AAALAC)](http://www.aaalac.org/index.html). This nonprofit organization now accredits more than 650 companies, universities, hospitals, government agencies and other research institutions throughout the world.

***Study Questions***

1. Why does the federal government have two sets of regulations governing the welfare of animals used in research, teaching and testing? Can you think of an advantage of this arrangement?
2. Most research institutions have animal use activities that fall under at least one of the two federal regulations discussed above. What is an example of an institution or situation in which the animal use would not be specifically covered by either of the regulations?
3. After studying the US Government Principles, which one do you think is the most important to ensure research animal welfare?

**Understanding the IACUC**

IACUCs are sometimes criticized within their institution for inconsistency and over-interpretation of the regulations. However, it is the nature of the regulations that local interpretation is necessary, as discussed above. Researchers have legitimate wish for assistance in understanding the rules and satisfying requirements efficiently. But most institutions judge that it is the IACUC’s primary role to ensure that the institution remains compliant. The IACUC has federally-mandated responsibilities that, if not executed properly, can result in sanctions. These may include fines and loss of federal research funding, as well as public embarrassment.

Mandated IACUC composition may affect how IACUC business is conducted. IACUCs must include a non-scientist and a member not otherwise affiliated with the institution (community member). This has implications for both the verbiage in the protocol (i.e., understanding what’s being done) and accountability to the public. Many states have public records and open meetings laws that may also impact IACUC policies and procedures.

***Study Questions***

1. IACUCs are often criticized by animal rights activists for under-interpretation of the regulations and generally inadequate oversight. Why might the regulations, as written, cause some suspicion along these lines?
2. What do you think the purpose is of the unaffiliated IACUC member? From both the institutional and community perspective, what type of person would make a good unaffiliated member?

**Working with the IACUC – Protocol Review**

Animal use activities must be reviewed and approved by the IACUC before a project can begin. It is therefore important that research staff understand the process in their institution, including the timeline and deadlines for protocol review. The regulations do not require that all protocols be discussed at a convened IACUC meeting, but some institutions have judged it important to do so. More commonly, the IACUC assigns a “designated reviewer” to conduct the review. However, the regulations specify that there must be opportunity for every IACUC member to request discussion of a protocol at a convened committee meeting. ([A recent article](http://www.labanimal.com/iacuc/wolff1002.htm) discusses the distinction between full committee and designated reviewer modes of review.)

There usually are institution-specific instructions available for completion of the protocol-review process, and consultation is typically available from an IACUC office as well as IACUC members. There often is a mechanism for “pre-review” of protocols before distribution of a final draft to committee members. Veterinary staff are also available for consultation, and should be contacted if projects involve potential for a pain or distress (more below).

Research staff also should be aware that, in addition to issues directly related to the protocol review process, there may be institutional requirements for training, facility orientation and security measures, and enrollment in an occupational health and safety program (more below).

Any significant change in an approved animal use activity must be reviewed and approved by the IACUC. This typically is handled through an amendment or addendum process with institution-specific paperwork. As with initial review, there must be opportunity for every member to request discussion at a convened committee meeting. A [recent notice from NIH](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-046.html) clarifies the specific issue of whether personnel changes are “significant,” and includes links to information on other significant changes.

Regulations require “continuing review” of all approved animal use activities. The AWARs require annual review; lack of details in the regulations means that there may be significant differences among institutions in how this is handled. The PHS Policy requires “de novo” review of animal use activities every three years, and this usually means submission of new paperwork.

*Difficult Issues in Protocol Review – Potential for Pain and Distress*

Minimizing pain and distress, consistent with meeting experimental objectives, is a key feature of the regulations and IACUC/institutional responsibility. (See, for example, [US Government Principle IV](http://grants1.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples).) The IACUC will need to know what the potential is for pain or distress associated with experimental manipulations, including clinical and behavioral abnormalities associated with spontaneous or induced animal models (e.g., mutant and transgenic mouse strains).

By regulation, veterinary staff must be consulted in the planning of studies involving potential pain or distress; planning may involve both the preparation of the protocol for IACUC submission and training in the experimental methods. Veterinary consultation is valuable for understanding:

* regimens for use of anesthetics, analgesics, and tranquilizers, including monitoring;
* how to recognize species-specific signs of pain and distress;
* surgical approaches and aseptic technique;
* post-procedural monitoring and intensive care.

Regulations also require that the PI consider alternatives to potentially painful or distressful procedures. The IACUC, through the protocol review process, must determine that this has been done appropriately. Alternatives are taken to mean not just **replacement** of animals with non-animal methods, such as computer simulations, but also **reduction** of animal numbers to the minimum necessary to satisfy experimental objectives, and **refinement** of methods to minimize pain and distress. Current regulatory expectations are that, in most cases, the PI perform a literature search for alternatives. Unfortunately, when done properly, this can be a time-consuming process. See the [Alternatives](http://ori.hhs.gov/education/products/ncstate/alternatives.htm) section of this website for additional discussion and resources.

One of the hardest jobs for both research staff and the IACUC is discussion and evaluation of methods to minimize pain and distress. This involves an inevitable balancing act, or cost-benefit analysis, between the experimental objectives and animal welfare. When there is potential for pain or distress, researchers are expected to carefully monitor animals and relieve the pain or distress whenever possible. One method to accomplish this is by administration of anesthetics or analgesics. By regulation, a specific scientific justification must be provided whenever anesthetics or analgesics are withheld in painful conditions; this might be necessary when the drugs would interfere with the interpretation of experimental data. Pain and distress also can be reduced by euthanizing the animal, and defining so-called humane endpoints (e.g., limits on size of tumors in cancer studies) is an important part of protocol preparation and review.

The AWARs require that research facilities file an annual report that accounts for numbers of animals used, by species and category of pain or distress (see sidebar). Many IACUCs require that this information be provided in the protocol form, and the IACUC may provide additional guidelines for determining the appropriate category. (Some institutions use a different system for categorizing pain and distress.)

This determination is not always straightforward, as illustrated below in the Study Questions.

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| According to the AWARs, an annual report must be filed with the USDA. Among other things, the Report must:   * State the common names and the numbers of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes (Category B). * State the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported with this group (Category C); * State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used (Category D); * State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report (Category E) |

*Difficult Issues in Protocol Review – Justification for using animals, species, and numbers used*

[US Government Principle II](http://grants1.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples) states that research using animals “…should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.” Protocol forms typically have a question that asks about the purpose and importance of the work, and PIs should use this as an opportunity to provide basic background information so IACUC members can understand why the animal use activity is necessary.

Regulations require that the PI provide a justification for using animals, and for the specific species and numbers of animals to be used. These are sometimes difficult issues to address, but involve basic questions that should be considered in the planning of any experiment using animals. Implicit in these questions is the notion that animals should not be wasted.

It may sometimes seem obvious why animals are needed for a particular experiment, and in some cases, this may be so. However, the prevailing view is that animals should not be used in research, teaching or testing unless there is no other way to accomplish the objectives of the activity. The need to use animals should be articulated in the protocol form.

The species of animal to be used is relevant to protocol review because the characteristics of a particular species (anatomy, physiology, behavior) might be absolutely necessary for the success of a study. Conversely, use of the wrong species could prevent a successful outcome.

Appropriate numbers of animals are also an important consideration in avoiding unnecessary or wasteful use of animals. There is a common misconception that this means that animal numbers must, as a priority, be minimized. In fact, properly understood, the requirement to justify animal numbers means that there has been due consideration of the experimental design of an experiment, including determination of the optimal number of animals per treatment and appropriate use of controls. Use of too few animals in an experiment may fail to yield interpretable results and is therefore also potentially wasteful. Proper experimental design includes statistical considerations, and some IACUCs may have expectations for consultation with a statistician. Some committees have statisticians as members, in order to provide advice in this area. The [Animal Welfare Information Center](http://www.nal.usda.gov/awic/pubs/IACUC/stat.htm#www) has useful information and web links to assist with statistical considerations and animal numbers. Of course, not all use of animals (e.g., teaching) involves experimental design in this sense. IACUCs are still expected to determine that the numbers of animals requested are appropriate for the intended purpose.

*Difficult Issues in Protocol Review – The Lay Summary*

There is no regulation for a “lay summary,” but many IACUCs ask for descriptions of animal use written in non-scientific terms. This seems important because the IACUC must include at least one non-scientist, and there is a presumption that all IACUC members be sufficiently informed to evaluate a protocol. Even other scientists may have difficulty in understanding a description of animal use if written in highly technical language specific to a particular area. One suggestion is for the PI to enlist support staff to help with this description.

*Difficult Issues in Protocol Review – Personnel qualifications and training (more below)*

The IACUC must determine that personnel working with animals are adequately qualified to perform the procedures described in the protocol; this includes everything from basic animal handling to anesthesia support and surgery to euthanasia. Thorough training of personnel is one of the most important refinements that can be made in studies using animals. Some institutions, especially in industry, rely on detailed training records to document individual qualifications. However, many IACUCs rely on descriptions of qualifications provided in the protocol form. Some research staff with years of experience and/or advanced academic degrees may feel offended by having to describe their qualifications for working with animals. However, the IACUC remains in the sometimes awkward position of having to ensure that personnel are qualified, and detailed information may be required in the protocol form.

*Difficult Issues in Protocol Review – Expired protocols*

One area that causes friction between the IACUC and research staff is when protocols expire. As discussed above, regulations require continuing review of approved activities, either annually (AWARs) or every three years (PHS Policy). Unfortunately, there is no provision in the regulations for extensions of approval or grace periods, and use of animals without an approved protocol, including one that has expired, is considered an area of serious noncompliance. (Among other things, serious noncompliance must be reported to OLAW.) While it is important that institutions have mechanisms to remind PIs of upcoming expirations, the PI also must recognize the importance of filing appropriate paperwork in time for adequate IACUC review and approval.

*Difficult Issues in Protocol Review – Blanket Protocols, Pilot Studies, and Expedited Review*

IACUCs as well as PIs are interested in ways to reduce the burden of protocol preparation and review, and there is legitimate interest in facilitating the process. However, IACUCs remain responsible for ensuring that regulations are satisfied, and that means that certain information (as discussed in this section) must be reviewed and approved before an activity can begin. Some research labs may perform standardized procedures on a regular basis, but protocols that describe just those procedures, without providing details of the overall experimental design (so-called blanket protocols) may not satisfy regulatory expectations. Similarly, although there is legitimate interest in performing relatively small, quick experiments to establish feasibility of a new hypothesis or product (pilot studies), there is no regulatory provision for granting approval for such work without satisfying the requirements discussed above.

There is often discussion about expedited review, usually taken to mean a mechanism whereby protocols can, for whatever reason, be reviewed on a fast track. While there are a number of ways to streamline the process of protocol review, two key considerations for the timing of review remain: all the required information must be in the protocol (or appropriate addenda or amendments), and all IACUC members must be given opportunity to request discussion of a protocol (or significant changes to the protocol) at a convened committee meeting. Institutions differ widely in how they handle these concerns, and institutional policies should be reviewed.

*Difficult Issues in Protocol Review – Delays and Withheld Approval*

Probably every IACUC has received occasional complaints about delays in approving a protocol. Most IACUC members are themselves PIs and animal users, and therefore sensitive to these concerns. But it is also understandable when otherwise busy IACUC members are unable to complete their review of a protocol in the most timely fashion.

Many “routine” delays in protocol approval are due to the need to obtain additional information from the PI or to clarify responses in the protocol form. A protocol may also be delayed by being referred to a convened IACUC meeting. Some institutions bring all protocols to convened meetings, but all IACUCs must have a mechanism for committee members to request such review. It is generally good advice for research staff to keep in contact with the institution’s IACUC office to ensure that review is proceeding on schedule.

IACUCs have the authority, at a convened meeting, to withhold approval of a protocol, but it is apparent that actually taking a vote to do this is a rare event. More common is for a committee to delay approval until additional information can be obtained. In any event, the delay can be frustrating to research staff, particularly if the protocol must be brought back to the next convened meeting. In most cases, a protocol will be assigned to a committee member (designated reviewer or primary reviewer) prior to being discussed at a convened committee meeting. Communication between the PI and this reviewer is often key to obtaining approval. Strategies that PIs should consider if they perceive unnecessary delays in consideration of their protocol involve contacting the chairperson of the IACUC and either requesting a new or additional reviewer, or requesting to attend a convened IACUC meeting to address concerns directly.

***Study Questions***

1. To what USDA Category should animals in the following be assigned?

* Guinea pigs will be euthanized for collection of liver tissue. Animals are sedated prior to euthanasia in a carbon dioxide chamber.
* Dogs are used to optimize conditions for radiography. The procedure is not painful, but animals must be anesthetized to prevent movement.
* Rabbits will be used to study the course of a bacterial infection. The infection causes illness after 24 hours, but the PI will euthanize animals 12 hours after being infected and expects no clinical signs.
* In a follow up to the above study with rabbits, the PI wants to evaluate the infection at a later stage. However, the rabbits will be euthanized at the first sign of infection.

1. The USDA has stated that, for the purposes of both the search for alternatives and in reporting, surgical procedures are considered potentially painful. Assuming that appropriate anesthesia is used, does this seem a correct interpretation?
2. Should all protocols be reviewed at a convened committee meeting? Should institutions specify certain types of protocol that will be discussed at a meeting? What are the advantages (and disadvantages) to either of these approaches?
3. As an IACUC member, what types of information would you want to see in order to assess a person’s qualifications for conducting an animal study?

**Working with the IACUC – Suspension of an Activity**

The IACUC has the authority, at a convened meeting, to suspend an activity (protocol) it has previously approved. This, like withholding approval of a new protocol, is an uncommon event, and one that both the IACUC and research staff would prefer to avoid. Suspension of an activity is a matter of ensuring institutional compliance; it usually is done when the committee learns that a researcher is conducting an animal-use activity without prior approvals. While it may be difficult, especially in a large/busy research laboratory, to keep up with all the activities, it remains the PI’s responsibility to notify the committee whenever there is a significant change in the work (see above). This includes not only changes in direction and addition of new studies, but also reporting any unexpected results that might affect animal welfare.

**Working with the IACUC – Personnel Qualifications and Training**

Although there are specific requirements for IACUC consideration of personnel qualifications (see above), the ultimate responsibility for ensuring that personnel are adequately qualified to work with animals rests with the institution. There is wide variability in how institutions accomplish this. There may be a series of seminars or workshops for research staff, and/or on-line instructional materials; attendance or completion of a course may or may not be mandatory. There is no regulatory requirement that personnel pass a test, but many institutions include an examination and/or some type of certification of course completion. The AWARs specify that training must be *available*in certain areas (see sidebar), but probably most institutions have judged that some level of training is required for all animal users.

Many if not most institutions require completion of some type of training before an individual can use animals, and some may require follow-up refresher courses or re-certification. Research staff should review their institution’s policies in order to avoid delays in beginning a project.

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| **Personnel Training Components (from the AWARs)**  Training and instruction of personnel must include guidance in at least the following areas:   * Humane methods of animal maintenance and experimentation, including:   (i) The basic needs of each species of animal;  (ii) Proper handling and care for the various species of animals used by the facility;  (iii) Proper pre-procedural and post-procedural care of animals; and  (iv) Aseptic surgical methods and procedures;   * The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress; * Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility; * Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act; * Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:   (i) On appropriate methods of animal care and use;  (ii) On alternatives to the use of live animals in research;  (iii) That could prevent unintended and unnecessary duplication of research involving animals; and  (iv) Regarding the intent and requirements of the Act. |

**Working with the IACUC – Semiannual Inspection of Facilities**

The IACUC must inspect facilities (and evaluate animal care an use programs) at least every six months. [Current interpretation from federal agencies](http://grants1.nih.gov/grants/olaw/references/faq_labanimals1997.htm#8) is that this schedule applies to all housing areas (animals kept more that 12 or 24 hours, depending on the regulation), but also includes places where there is survival surgery. Investigator laboratories in which animals are used also must be inspected, although frequency of inspection should depend on nature of animal use in that area. The IACUC remains responsible for all areas where animals are used.

IACUC members (as well as research staff) are often uncomfortable with inspections of research laboratories, in part because of traditions of academic freedom and independence, but also because there are no regulatory criteria for inspection of these areas. While these inspections have an important oversight component, most IACUCs view these inspections as an opportunity to visit with research staff about current procedures involving animals, staff training, participation by staff in the occupational health program, etc.

***Study Question***

There is no regulation to guide IACUCs on whether inspections should be announced (scheduled in advance with the PI or laboratory supervisor) or unannounced, and the latter can certainly be a source of irritation for research staff. What are some arguments for each approach?

**Working with the IACUC – Occupational Health and Safety**

According to both the *Guide for the Care and Use of Laboratory Animals* and the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*, institutions must provide an occupational health program for personnel who work with animals. The discussion in the [*Guide*](http://www.nap.edu/readingroom/books/labrats/chaps.html#occ) provides an overview of program components, but also refers to a more comprehensive NRC document, [*Occupational Health and Safety in the Care and Use of Research Animals*](http://www.nap.edu/books/0309052998/html/index.html)*.*

Coordination and administration of this program is typically the responsibility of the institution’s health and safety office, but the IACUC is responsible for evaluating adequacy of the program as part of its required semiannual evaluation of facilities and programs. There is substantial flexibility in the regulations with respect to details of the occupational health program and, accordingly, wide variation in institutional requirements. (As an example, click here to see a description of the [program for North Carolina State University](http://www.ncsu.edu/ehs/www99/right/handsMan/animal/animal.html).) As with the personnel training program, the institution may link final protocol approval to enrollment in the occupational health program.

**Working with the IACUC – Review of Concerns**

A specific responsibility of the IACUC is to review and investigate any concerns related to animal care and use. Concerns may come from public complaints, or from within the institution. This regulation has several implications for research staff. First of all, it is a mechanism to voice an animal welfare concern that they may witness, e.g., improper care or treatment of animals by animal care staff or other researchers. Second, a concern could be brought against a researcher, e.g., improper handling of one of their animals. Finally, all staff should be aware that so-called whistle blower protections are required by the AWARs. This means that someone who brings a concern to the IACUC may be legally protected against discrimination or reprisal.

There are other mechanisms for individuals to express concerns about how animals are cared for or used, and personnel are encouraged to use these avenues first (e.g., contacting supervisory, management or veterinary staff in the animal care unit). Research staff should be familiar with their institution’s key personnel involved with animal care, as well as the specific mechanism to bring concerns to the IACUC.

***Study Questions***

1. Do you think the IACUC should act on anonymous complaints about improper animal care or use?

2. How should the IACUC go about conducting an investigation of animal welfare concern?

**Advanced IACUC Resources**

There are a number of excellent resources to help guide institutions and IACUCs in formulating institutional policy and executing their responsibilities.

The [IACUC Handbook](http://www.crcpress.com/shopping_cart/products/product_detail.asp?sku=1685) is a comprehensive, multi-authored text that examines all facets of IACUC responsibility. The question and answer format is especially useful, with answers that provide both specific regulatory references and comment/opinion.

Another comprehensive resource is the second edition of the [IACUC Guidebook](ftp://ftp.grants.nih.gov/IACUC/GuideBook.pdf), from the Applied Research Ethics National Association (ARENA) and the Office of Laboratory Animal Welfare (OLAW). This revised edition “…is the product of an ARENA-established editorial board of knowledgeable individuals who have IACUC experience and are familiar with the evolution of IACUC issues and relevant documents published during the past decade.”

[OLAW](http://grants1.nih.gov/grants/olaw/olaw.htm) offers “a [tutorial](http://grants1.nih.gov/grants/olaw/tutorial/index.htm) for new animal care and use committee members, institutional administrators, investigators, animal care personnel, veterinarians, or others who are interested in learning about the PHS Policy.”

There has been widespread interest by institutions and, especially, new IACUC members in the ARENA “IACUC 101” workshop. “ARENA IACUC 101 is a full day didactic and interactive training course for new as well as seasoned IACUC members…The program is delivered by a top-notch faculty renowned for their expertise in institutional animal care and use issues and program development including representatives from both private and academic biomedical research institutions as well as the AAALAC, USDA and OLAW.” Information on upcoming workshops can be found on the [PRIM&R](http://www.primr.org/EducationalPrograms.html) web site.

The [ResearchTraining.org](http://www.researchtraining.org/) site was developed by the Veteran’s Administration Office of Research and Development to meet mandates for research training, including “Essentials for IACUC Members.” It is offered free, and the course may be taken through the institution or as an unaffiliated “public” member.

A useful article on training for IACUC members is [“IACUC Training: From New-Member Orientation to Continuing Education.”](http://www.labanimal.com/iacuc/james0602.htm)

[IACUC Central](https://www.aalas.org/iacuc/training-resources/iacuc-members-staff#.VqzQrDYrLox) is a web site hosted by the American Association for Laboratory Animal Science (AALAS) that collects much of the available internet information.

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