Avoiding an Overzealous Approach: A Perspective on Regulatory Burden

J.R. Haywood and Molly Greene

Abstract

The authors discuss the impact of regulatory burden on the research enterprise, with emphasis on animal care and use programs. They identify three sources of regulatory burden: specific requirements in law and regulation, interpretive requirements or "guidance" by regulatory agencies, and self-imposed regulatory burden resulting from institutional interpretations. Attempting to minimize the risks of noncompliance through the overzealous application of "requirements" does not necessarily benefit the animals. Balancing risks associated with animal research and burden in a successful program requires clear and consistent communication among all stakeholders—the institutional leadership, institutional animal care and use committee (IACUC), attending veterinarian and staff, and scientists. An evaluation tool is provided for institutions to assess their approach to required and voluntary activities in their animal care program. Drawing on the knowledge and experience gained in a combined 40 years of serving on, managing, training, and evaluating animal care programs, the authors conclude that institutions must thoughtfully balance their research and compliance needs to successfully maintain their institutional goals. They stress that a culture of compliance based on knowledge of the regulations, dedication to quality animal care, reasoned use of science-based performance standards, and the judicious application of professional judgment is the foundation for facilitation of research in the context of animal welfare and regulatory compliance.

Key Words: compliance; institutional animal care and use committee (IACUC); regulations; regulatory burden; risk assessment

Overview

Institutions must comply with federal, state, and local laws and regulations governing the care and use of animals in research, teaching, and testing. In addition, the public expects oversight of research. For both publicly and privately funded research, oversight is part of the social contract between scientists and funding agencies that is implicit with the privilege of performing research, working with research subjects, and using public facilities and funds. Every program must ensure the protection of the research subjects.

An animal care program need not, however, go above and beyond regulatory requirements to achieve exemplary status, as such efforts are often without material benefit to the animals and at significant cost to the facilitation of research with animals. Yet in the mosaic of research oversight (which includes not only animal care but also human subject protection, biohazard use, export controls, financial controls, and numerous other activities) an institution may attempt to mitigate all risk regardless of cost, and in doing so lose sight of the balance that is essential to promoting rather than impeding research. Each institution's financial commitment to compliance directly affects the kinds of activities it can support as well as the design and implementation of its compliance programs. Thus a clear understanding across the institution of the fiscal realities and the resources available to meet the needs of the institution is imperative to provide the framework necessary for evaluating the types of oversight programs that can and should be instituted.

Regulatory Burden on Scientists

The role of the scientist in the oversight mosaic is very important. Managing a laboratory in today's compliance environment is challenging, and the greater the demands placed on the laboratory by multiple oversight offices, the more difficult it is to achieve compliance in all areas. In a recent study by the Federal Demonstration Partnership, scientists estimated that 42% of the time that they dedicated to federal research projects was spent on administrative activities, and regulatory-related activities (including those for the institutional animal care and use committee, IACUC[1])

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[1]Abbreviations used in this article: AAALAC, Association for Assessment

were near the top of their list (Decker et al. 2007). When extrapolated over all research activities, approximately 24% of their time was devoted to pre- and postaward administrative duties. There will always be a level of tension between program oversight and research scientists, but one of the major roles of the IACUC, whose members are primarily active research scientists, should be to reduce this tension in order to facilitate the research. The committee can help educate scientists about its oversight role, and the scientists can educate the committee about their prerogatives and needs.

Approximately a decade ago, the National Institutes of Health (NIH), under a mandate from Congress, undertook a study to assess the impact of regulations in five areas of research compliance, including animal care and use. For that assessment, regulatory burden was defined as any aspect of federal legislation, regulation, or policy, or any federal or research institution practices that could be made more efficient without diminishing intended protections (Mahoney 1999). The NIH Initiative to Reduce Regulatory Burden identified several areas of regulatory burden, including overlap of oversight, duplication of effort to respond to multiple agencies, and unnecessary preparation, review, and approval of animal use protocols that were never funded (Mahoney 1999). Although agencies involved in the oversight of animal research have worked together to reduce their duplicative efforts and to implement "just-in-time" review, many of the committee's other recommendations have gone unheeded. One of these recommendations called on the research community to consider that much of the burden was the result of its overinterpretation of regulations and policies.

Federal Regulatory Agencies and Requirements

Excessive and increasing regulatory burdens are very real to institutions and compliance with federal regulations is one of the fastest rising costs in universities today (Goldman et al. 2000). A Google search of the terms "research" and "regulatory compliance" produced over 3,400,000 citations. What are the sources of compliance-related burden in the oversight of animal research and teaching? Can these burdens be lessened without compromising animal welfare?

Clearly, the number of entities that have a role in overseeing animal care and use leads to some confusion and excess. At least eleven governmental and nongovernmental agencies have policies or regulations in place or under development to protect animals in research, teaching, and testing. Furthermore, these agencies use a variety of reference documents that institutions must follow. Institutions and their scientists must be cognizant and compliant when approving and submitting the large variety of documents generated and required by these agencies.

Over the years, another important factor has emerged in the interface between agencies and the research community. Agencies that constantly expand guidance and policies require a higher level of institutional attentiveness and implementation than those that allow institutions to comply within broad guidelines. As such expansion has increased across agencies, the research community's compliance efforts have shifted from the application of performance-based standards and professional judgment to increased adherence to guidance and direction by oversight agencies. The result has been less institutional decision making and a greater sense of regulatory oversight. And because many institutions do not distinguish between "guidance" and "regulation," both become de facto requirements.

Balancing Risk and Regulatory Burden

Managing risk against burden in an animal care program is a slippery slope. Latitude in the application of policies and regulations that guide oversight of animals in research, teaching, and testing leaves room for the implementation of best practices and professional judgment. However, many times one person's best practice is another's regulatory burden, because a "best practice" may go well beyond the regulatory requirements. Such discrepancies in interpretation contribute to the continuing debate among animal care programs about best practices that "go too far" and then either become mandates or are perceived as mandates.

Institutions that err in an overzealous direction by exceeding regulatory requirements create their own burden on scientists, staff, and research projects. This is where the balance with risk comes into play. Because there is little tolerance for risk in the research community, few institutions take the time to weigh the risks associated with implementing best practices that are beyond requirements for compliance against the actual policies and regulations. The risks associated with self-imposed regulatory burden include

- alienation of scientists and attempts to avoid compliance,
- difficulty in recruiting new scientists to the institution,
- scientists' avoidance of the use of animals in research because of the increased costs of compliance,
- subsequent missed funding opportunities and failure to pursue potentially important research that must be done in animals, and
- diversion of money available for the actual care of animals to compliance efforts that may have little if any impact on animal welfare.

Thus the balance between risk management of an animal care program and regulatory burden is of interest to all

and Accreditation of Laboratory Animal Care International; IACUC, institutional animal care and use committee; OLAW, Office of Laboratory Animal Welfare; PHS, United States Public Health Service

stakeholders. It is especially important to the credibility of the program and how it is perceived both in the institution and in the broader research community. As the tolerance for risks goes down the cost of compliance and the need for excessive risk management go up.

Major Sources of Regulatory Burden

For this article, we have identified three major sources of regulatory burden to institutions. First, there are some legally mandated regulations that are intended to protect animals but may actually do little to contribute to the animals' health and well-being. Second, some policies and guidance issued by oversight entities that extend beyond the regulations, without basis in law, may or may not benefit research subjects. Finally, a third source of burden is institutional administrative reactions to agency-promulgated policies and guidance that lead to excessive internal procedures, even though they may be considered best practices by some.

In the next few pages, we share our perspective on the delicate balance of managing risk and managing burden by looking at these sources of burden in an animal care program. We explain how overzealous approaches have led to an increased and unnecessary burden on animal care programs and how the appropriate assessment of risk factors can allay the burden. Using case studies and specific examples, we offer suggestions to consider in assessing risk and burden in an animal care program. We do not prescribe a specific model for all institutions to follow, nor do we suggest that regulatory compliance is optional. We hope to demonstrate the impact of the evolution of the regulatory environment and the importance of considering change that will both encourage research and maintain compliance without creating an increasingly constrictive environment.

Burden Resulting Directly from Regulations

The complex system of oversight of animal research and teaching in the United States has evolved because Congress and oversight agencies have wanted to assure the public that measures are in place to protect the acquisition and use of animals as research subjects. The Animal Welfare Act (AWA) and Health Research Extension Act (HREA) led to regulations and policies that have been successful in ensuring the protection of animals as research subjects. These oversight mechanisms exceed the requirements of most other countries for the humane care and use of animals in research, teaching, and testing.

The success of the American system in protecting animal research subjects is due, in part, to its extensive requirements, some of which—for example, a twice-yearly review of an institution's animal care program—are likely to be more than is necessary to protect research subjects. An annual review, combined with other programmatic activities, veterinary oversight, and thorough protocol review, should be adequate to assess the functional components. For large well-run programs, semiannual reviews require a considerable number of person-hours without evidence of measurable advantage for the animals, and poorly run programs no matter what size are not likely to benefit from an additional review.

Another example of an excessive requirement is a component of the annual report to the US Department of Agriculture (USDA). Whereas the AWA requires a report of "information on procedures *likely* to produce pain or distress in any animal" (emphasis added; AWA 2007), the USDA's Animal Care Policy #17 requires a retrospective reporting of procedures that were painful (USDA 2006); retrospective reporting takes a considerable number of person-hours without appreciable benefit to the animals.

An increase in burden from the passage of a law to the development of regulations is further illustrated in the relationship among the NRC *Guide for the Care and Use of Laboratory Animals* (originally published in 1963), the United States Public Health Service (PHS[1]) Policy on Humane Care and Use of Laboratory Animals (first published in 1971), and the Health Research Extension Act (passed in 1985). The *Guide*, which is not a legal document and predates the HREA, PHS Policy, and Animal Welfare Act (enacted in 1966), has long been considered the guiding standard for the development and implementation of an animal care program based on scientific literature and best practices developed over time. The passage of the Health Research Extension Act in 1985 provides the statutory mandate for the PHS Policy (see PHS Policy Preface), which requires that assured institutions base their programs of animal care and use on the *Guide* (PHS Policy, footnotes 2, 7, 9, 11, and 13). This suggests that the *Guide* is thus no longer a guide but a regulatory document and that "should" phrases are really "must" phrases, as with the Act. The ramifications could be extensive for assured institutions given the requirement for the semiannual report to "identify specifically any departures from the provisions of the *Guide*" (PHS Policy, IV.B.3) and for the annual report to the NIH Office of Laboratory Animal Welfare (OLAW[1]) to include "any serious deviation from the provisions of the *Guide*" (PHS Policy, IV.F.3.b), as neither "departures" nor "serious deviations" are defined in the PHS Policy or the *Guide*.

These are examples of required regulatory burden that may impose major impediments to an animal care program and to productive animal research. The original intention of the laws was to protect research animals without obstructing the research process, and the basic laws and regulations generally achieve that goal. Unfortunately, the US regulatory system does not provide a "sunset" proviso for regulations. Consequently, there is no mechanism to periodically evaluate the effectiveness of laws and regulations to determine whether they are having the desired impact or to evaluate their cost in order to conduct a cost-benefit analysis.

The continual issuance of new interpretations of federal regulations in the form of policies and guidance increases

the costs of compliance with no commensurate increase in funding from the federal government or funding agencies. Meanwhile, dwindling resources resulting from reduced funding to universities, decreases in the spending power of grants and indirect cost return, and the demand for ever-increasing corporate profits by stockholders all make the costs of compliance increasingly challenging and expensive and limit research productivity.

The amount of time it takes for research staff to complete compliance paperwork, serve on compliance committees, and participate in compliance training further exacerbates the problem. A 2000 Rand report (Goldman et al. 2000) calculated an overall underrecovery of costs for research compliance and maintenance of the research environment at between $700 million and $1.5 billion annually. It is highly likely that those figures have increased, not decreased, in the 8 years since the report was written, representing substantial funds not available to and/or diverted from research activities.

Interpretive Regulatory Burden

Increases in the complexity of oversight may be part of the natural evolution of organizations. The unintended consequences of trying to clarify situations or helping protect institutions has led to interpretations and agency policies that may theoretically lead to a best practice but exceed those required by regulations. For example, occupational health expectations have risen dramatically over the last decade to a state well beyond any written requirement. In fact, PHS Policy indicates only that an institution must have an occupational health program and that it must be described in the institution's Animal Welfare Assurance (PHS Policy, IV.A.1.f); the USDA is silent on the subject. The actual "requirement" is found in the *Guide for the Care and Use of Laboratory Animals* (NRC 1996) and the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (FASS 1999, originally published in 1988). Compliance with this "requirement" runs the gamut from a simple opt-out statement to a full physical with associated diagnostic tests by a physician, at considerable expense to either the individual or the institution. An educational component, a risk assessment, and a tracking system are important to an occupational health program, but many institutions go well beyond these. With the exception of prevention of tuberculosis in nonhuman primates, it is difficult to demonstrate the benefit to animals of this expensive requirement. With some aspects, it is also difficult to demonstrate the benefit to humans.

Another interpretive regulatory burden with which nearly every institution struggles is associated with USDA's Animal Care Policy #12 (Consideration of Alternatives to Painful/Distressful Procedures). While the intent (no unnecessary activities that may cause pain and/or distress; relief from pain and/or distress) was to benefit animals, the interpretation and implementation have become a paper exercise for the research staff and the IACUC, and have all but created a cottage industry for those who know how to do literature searches that will satisfy inspectors that alternatives have been considered. For scientists, literature searches are part of the process of planning their research, but satisfying the requirement often diverts them from their obligation to funding agencies to design the most rigorous experiments for testing the proposed hypotheses. This, of course, leads to additional tension between the scientist and IACUC in other areas such as scientific review of the protocol and justification of the numbers of animals necessary to demonstrate statistically significant data.

In the situations described above and others, suggested best practices may be of little benefit to animals but the additional workload requiring more personnel and increased costs (in terms of money, time, and political capital) can be significant. These examples also illustrate that with the development of the current oversight system there has been greater focus on detailed documentation and paperwork than on the care and well-being of animals and facilitation of the research. This shift in emphasis represents a challenge for institutions and scientists and is primarily responsible for the increase in compliance costs. However, a critical factor contributing to these costs is how an institution chooses to respond.

Internal Sources of Burden

As mentioned above, some of the areas identified as regulatory burdens by the 1999 NIH study were, in fact, self-imposed, not the result of the regulations themselves or even overinterpretation of the regulations by the agencies. Many institutions do not actively manage, or even consider, the balance between risk and burden. Without careful consideration of the impact of best practices, suggestions, and guidance through professional judgment and performance-based standards, it is inevitable that a program will increase the burden of cost, time, and resources.

The question that each institution must address with all stakeholders is: "What kind of program will best serve the institution's mission of research, teaching, and/or testing?" The goal of many institutions is to strive for an exemplary program with shiny new facilities, meticulous paperwork, and enough people in place to ensure that every detail is addressed completely. Institutions may pursue this goal for a variety of reasons: out of fear of having a less than perfect program when the USDA or Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC[1]) come to visit, as overcompensation for recent or past problems, in response to the insidious slow creep of continuously increasing expectations, or based on a decision to adopt a "zero risk" approach to the program. Whatever the reason, the result is usually that the institution's overzealous compliance with the required regulations and policies leads to overinterpretations and impediments to research programs. Thus institutions make their own regulatory burden.

One example of institutional overzealousness is the triennial rewrite of animal use protocols, a requirement related to—but not actually stated in—the PHS Policy (IV.C.5; NIH 2002): "The IACUC shall conduct . . . a complete review . . . at least once every three years." Examination of the requirement reveals simply that the IACUC is directed to conduct a triennial review; no mention is made of a requirement for the scientists to rewrite the protocol. In placing this burden on the scientists, IACUCs frequently extend this PHS-specific requirement to all research and teaching activities regardless of source of funding. To further complicate this process for the scientists, most IACUCs treat this rewrite as a new activity, going so far as to assign a new tracking number even though it is an ongoing study. While this may be a relatively easy "cut and paste" task if appropriate amendments and modifications have been made during the preceding years, it still represents part of the burdensome "administrative effort" cited in the Federal Demonstration Partnership report (Decker et al. 2007). We suggest that, unless there is a substantive change in the direction of the research, IACUCs conduct a triennial review in a less burdensome and perhaps more useful manner by approaching it as an opportunity for postapproval monitoring, assessment of progress to date, and plans for the future direction of the project.

It can be difficult to find the right balance between acceptable compliance and the highest-quality program, but it is possible to do so without imposing an excessive burden on the scientists or on the research and animal care programs. It is up to the institution and its leadership to define the measures of the quality of their animal care program and to foster the culture necessary to achieve that quality. In order to do so, the institution must define its values and goals, understand the required regulations and policies, and identify the level of risk that it is (and is not) willing to accept with regard to the perceived best practices and the cost to the institution. A strong culture of compliance should be developed from the perspective of the scientist, considering the ease, rationale, and cost of implementing rules that must become part of the research process.

Assessing Your IACUC Activities for Regulatory Burden

We suggest that institutions review their IACUC practices to identify sources of self-imposed regulatory burden and determine the risk-benefit-cost ratio. The following questions can be helpful in assessing the necessity of IACUC practices:

- Why do we do this?
- Does it help the animals?
- Can the end be achieved in a more efficient, cost-effective manner? (This question is useful for required activities as well.)

Some examples of common—although not required—activities are shown in Box 1. All of these activities exceed those of a minimally compliant program; many are expectations of an AAALAC-accredited program.

Figure 1 is a diagram of the process we suggest for reviewing an institution's activities. In conducting a review, bear in mind that the greatest costs associated with regulatory burden are for the person-hours to conduct the "regulatory" activity and for research staff to implement or respond to compliance "requirements." Significant alterations to, or the discontinuation of, any activity described in the Assurance Statement or program description as a result of this analysis should be noted in the annual report to OLAW and/or AAALAC.

Case Studies

We posit two identical hypothetical institutions for the case studies below. To manage the workload associated with the review of 500 protocols, annual renewals, and/or modifications per year, both IACUCs have 11 voting members, far exceeding the USDA minimum of 3 and PHS minimum of 5. The average hourly salary (based on a 40-hour workweek) of the scientific faculty members of the IACUC at academic institutions is \$40,[2] plus approximately 30% in benefits, or a total of \$52 an hour. Meeting attendance is good and averages eight employee members and one nonaffiliated member, at a cost of \$416 an hour (eight members × \$52/hr, not including the salary of the nonaffiliated member, who is a volunteer).

If yours is primarily a medical institution, the salaries may be considerably higher, according to the annual salary survey conducted by the Association of American Medical Colleges: depending on rank and years of experience, clinical faculty average salaries range from \$96 to \$130 per hour and basic science faculty from \$44 to \$90 per hour (AAMC 2008). Using the median of these rates and the fact that IACUC members are predominantly basic science faculty, an hourly rate of \$62 plus benefits, or \$80, may be the best estimate for individual member costs. The meeting cost in this example would thus be \$640/hour for a medical school IACUC.

The average salary of these hypothetical committees is based on a survey of all faculty at all doctoral universities in the United States. Your institution's human resources office should be able to provide the average salary of your committee members to help calculate the cost of these activities.

Case Study 1: Protocol Review

This may be the single most time-consuming IACUC activity.

[2]According to the 4/20/07 *Chronicle of Higher Education* (Millman 2007), the range of average faculty salary for assistant through full professor at a doctoral university is between \$31 and \$55 an hour depending on rank and years of experience.

Box 1 Examples of self-imposed regulatory burden

These are examples of program components not required by law or regulations. Although in many cases they can rightly be described as best practices, they exceed the federal requirements. We suggest that institutions review their IACUC practices to identify similar sources of self-imposed regulatory burden to determine the risk-benefit-cost ratio using the process shown in Figure 1. It is advisable for institutions to involve all stakeholders in such a review before abandoning any current practices.

General

- Having an IACUC if exempt from USDA and PHS requirements and not AAALAC accredited
- Maintaining accreditation
- Appointing a committee of more than 5 members (3 if not receiving PHS funds)
- Extending USDA requirements to nonregulated species
- Extending PHS requirements to activities not funded by the Public Health Service
- Hiring personnel dedicated to postapproval monitoring
- Conducting postapproval monitoring of every protocol every year
- Reporting events to USDA, OLAW, and/or AAALAC that are not required to be reported

Semiannual review

- Inspecting areas not covered by USDA, PHS, and/or AAALAC
- Assigning more than two IACUC members to inspect each room in each facility
- Inspecting items not necessarily the responsibility of the IACUC (e.g., DEA logs and environmental health and safety issues)
- Having more than one individual inspect PHS-only activity areas
- Reviewing all policies and SOPs every 6 months, or even annually
- Conducting a semiannual or annual review of the AAALAC program description and/or PHS Assurance
- Documenting delivery or IO receipt of semiannual report
- Creating or using tools other than the checklists provided by OLAW and APHIS

Meetings

- Requiring all categories of IACUC membership (chair, attending veterinarian, nonaffiliated member, nonscientist, and scientist) to attend every meeting and every inspection
- Requiring unanimous approval votes
- Voting to approve minutes
- Voting to approve agenda

Protocol review

- Requiring protocols for invertebrate animals
- Allowing more than a week for members to request full committee review
- Requiring members to respond when notified of a protocol to be reviewed
- Tabulating responses to above
- Assigning more than one member for a designated member review
- Requiring investigators to submit a complete protocol application every year
- Requiring investigators to rewrite and/or submit a completely new protocol every 3 years
- Calling for a full committee review for all protocols regardless of the category of invasiveness
- Calling for a full committee review of every protocol every year
- Requiring literature searches on protocols that do not have the potential for pain and/or distress
- Requiring literature searches on protocols for activities involving nonregulated species
- Prereviewing all protocols
- Replicating literature search results by IACUC or staff
- Sending a complete copy of all protocols, all modifications, all amendments, and all continuations to every member
- Requiring IACUC (rather than administrative) review of minor protocol modifications
- Conducting annual review of protocols for nonregulated species
- Requiring every member to review every protocol and provide feedback to the primary reviewer(s)
- Circulating all IACUC member comments generated above to all IACUC members even if no IACUC member requests FCR
- Duplicating review of protocol for work that will be conducted at another institution
- Requiring the IACUC Chair's signature of approval on every protocol
- Requiring one-to-one protocol-to-grant correlation
- Conducting a statistical review of all protocols
- Reviewing PI publications during annual review
- Comparing protocols to non-PHS funded grants

(continued)

Box 1 continued

Minutes and recordkeeping

- Providing a verbatim record of discussion
- Providing a synopsis of proposed activities for protocols reviewed
- Recording the number of votes for and against as well as abstentions and/or recusals, except in cases of conflict of interest
- Recording who voted for, against, or abstained, except in cases of conflict of interest
- Recording the reason(s) a protocol was approved unanimously
- Recording who made motions and who seconded
- Maintaining records beyond the required 3 years
- Keeping a detailed record of minority views or of reasons for negative votes on protocols and other committee deliberations
- Requiring IACUC members' signatures on minutes

"Why Do We Do This?"

Self-response: We use species in addition to rats and mice, have PHS-funded activities, are AAALAC accredited, and are subject to USDA regulations, PHS Policy, and both *Guides*, all of which require review and approval of activities.

"Does It Help the Animals?"

Self-response: Definitely. Furthermore, both institutions made the decision to review protocols for all vertebrate animals because it is the right thing to do. Although this question is optional for required activities, it doesn't hurt to remind ourselves and others why we do what we do.

"Can the End Be Achieved in a More Efficient, Cost-Effective Manner?"

Self-response: Institution A requires full committee review of all protocols, annual renewals, and modifications. If 10 minutes are allowed for review of each protocol, the IACUC

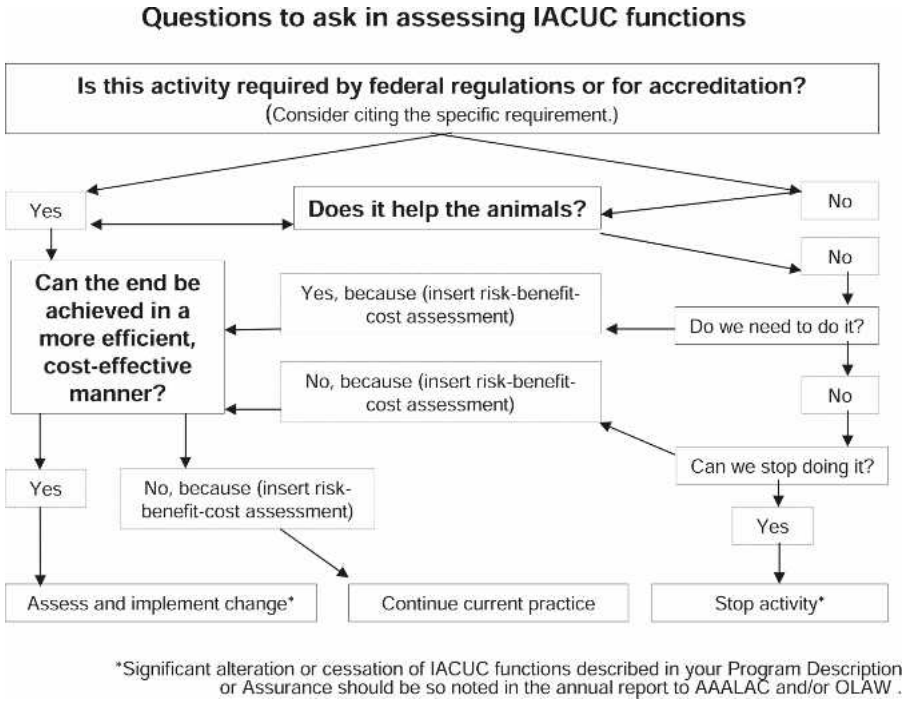

Figure 1

spends a minimum of 83 hours[3] in meetings reviewing protocols, at an annual cost of $34,528 for an academic institution and $53,120 for a medical institution.[4] To accommodate this workload, meetings are held twice a month.

Institution B uses designated member review for 95% of its protocols, annual renewals, and modifications and sends about 25 protocols a year to be reviewed by the full committee. Cost to review protocols in a convened meeting: $1,733 (academic) or $2,666 (medical) per year.[5] The institution's system of designated member review uses three committee members to ensure a quality review of each activity and each estimates spending an average of 10 minutes per review of each protocol, annual renewal, or modification. Annual cost for designated member review of protocols: $12,350 or $19,000.[6] Annual savings to the institution in protocol review alone: $20,000 to $31,000.[7] Those savings represent money the institution can devote to research rather than compliance efforts that are not necessarily value-added activities. Additionally, the convenience, efficiency, and speed of protocol review are increased considerably, providing better support to the scientists and helping to facilitate their research programs. The savings could be even greater if Institution B chose to have only one designated member review each protocol as allowed by both USDA and PHS, adding another $4,100 to $6,300 to cost savings.[8]

These figures do not include time spent reviewing and writing responses, inspecting, discussing and developing policies, or any other out-of-meeting IACUC activities. Furthermore, these costs are related only to the animal care and use committee; most institutions also have faculty committees evaluating human research protection, biological safety, radiation safety, chemical safety, conflict of interest, and other regulatory mandates.

[3]Calculation: 500 protocols × 10 minutes/protocol ÷ 60 minutes/hour.

[4]Calculation: 83 hours × either the $416 academic or $640 medical institution meeting hourly rate.

[5]Calculation: 25 protocols × 10 minutes/protocol ÷ 60 minutes/hour × either the $416 academic or $640 medical institution meeting hourly rate.

[6]Calculation: 475 protocols × 30 minutes/protocol ÷ 60 minutes/hour × either the $52 academic or $80 medical institution individual hourly rate.

[7]Calculation: *Academic institution:* $34,528 meeting time for full committee review –$1,733 for 95% full committee review meeting time –$12,350 designated member review time = $20,445. *Medical institution:* $53,120 meeting time for full committee review –$2,666 for 95% full committee review meeting time –$19,000 designated member review time = $31,454.

[8]Calculation: One designated member reviewer would probably increase review time to 20 minutes for each protocol, annual renewal, or modification: 475 protocols × 20 minutes ÷ 60 minutes/hour × either the $52 academic or $80 medical institution individual hourly rate.

Recommendation

Assess your protocol review process to determine whether it is possible to conduct a quality review more efficiently and effectively and thus reduce your self-imposed regulatory burden, improve the efficiency of the review processes, reduce associated expenses, and improve scientists' morale.

Case Study 2: Postapproval Monitoring

"Why Do We Do This?"

Self-response: Although technically not required by either the USDA regulations or the PHS Policy, most oversight entities expect it. According to the *Guide* (NRC 1996, 61), "A continuing and thorough assessment of surgical outcomes should be performed to ensure that appropriate procedures are followed and timely corrective changes instituted." The OLAW FAQ state that "Institutions are responsible for oversight of all animal-related activities regardless of how long or where the activity occurs" (OLAW 2007). And in 2000 OLAW and USDA published a joint opinion in *Lab Animal* (Potkay and DeHaven 2000, 36) stating that "If an institution fails to establish ongoing monitoring systems to ensure that the actual animal work being conducted is the same as that which the IACUC approved, this also contributes to noncompliance in some cases." Considering the sources of these quotes, many institutions don't think twice about instituting a formal postapproval monitoring program.

"Does It Help the Animals?"

Self-response: Maybe, maybe not. If the only intervention is a blood draw, maybe not. For survival surgery procedures, monitoring may benefit the animals; but if the surgeries are done by highly skilled technicians closely supervised by equally well trained scientists, it is not clear what will be accomplished by formal postapproval monitoring as described elsewhere in this issue (Banks and Norton 2008).

"Can the End Be Achieved in a More Efficient, Cost-Effective Manner?"

Self-response: Institution A has diverted the efforts of a full-time veterinary technician, with an annual salary of $40,000 plus benefits, or $52,000, to postapproval monitoring. After 2 years on the job, during which each of the 200 principal investigators' labs have been visited twice a year (because of PHS funding and consequent inspection requirements), incidents of protocol drift and noncompliance are about 5-10%. Although none of the drift or noncompliance constitute serious violations of any laws or regulations and no renegade scientists have been identified, the institution chooses to continue spending more than $52,000 a year

(plus space, supplies, and equipment) for this compliance activity.

Institution B conducts postapproval monitoring in a less formal manner in conjunction with routine IACUC and staff activities (Plante and James 2008). It, too, records incidents of protocol drift and noncompliance of about 5-10%. Institution B chooses not to implement a formal postapproval monitoring program until the risk outweighs the benefit of using the funds for research activities. The cost of this PAM is minimal, and the savings of more than $52,000 annually (plus space, supplies, and equipment) can be devoted to animal care and support of research.

Neither of the examples above takes into account the time the scientists and their staff devote to the PAM visits, time that could be spent on research and animal care activities.

Recommendation

Before increasing your self-imposed regulatory burden by implementing a formal postapproval monitoring program, conduct a thorough assessment of approved activities and of the history of compliance or problems. Review your program to determine which activities are candidates for close oversight and whether there is a sufficient number to warrant dedicating one full-time equivalent professional (or more) to this activity before adding this expensive, but not required, compliance component. A program that encourages open communication between scientists and the IACUC will benefit the quality of research and the care of the animals—and, because it is the right thing to do, it will achieve a high level of compliance without dedicated compliance monitors and for a lot less money.

Summary

In this article we have attempted to explain the development of animal care programs beyond the requirements set forth by law and regulation. We have observed that regulatory burden originates from specific regulations, agency interpretation of regulations, and institutional policies, procedures, and interpretations. Our goal has been to present a framework of ideas with which institutions can assess their programs according to their resources, their culture, and their long-term goals. This self-evaluation needs to be a team effort involving the institutional official, IACUC, attending veterinarian and staff, and scientists so that all perspectives are factored into determining the kind and size of program that the institution wishes to maintain.

A program that does not proactively balance research and compliance to avoid an overzealous approach creates greater risk to the animals, scientists, institution, and funding agency, whereas a culture of compliance based on knowledge of the regulations, dedication to quality animal care, reasoned use of science-based performance standards, and the judicious application of professional judgment provides the foundation for facilitation of research in the context of animal welfare and regulatory compliance. Using these guiding principles, the institution can implement a high-quality, even exemplary, program with minimum burden to the stakeholders.

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