Council on Governmental Relations Survey Report on Institutional Administrative Requirements for Animal Research

Introduction

The Council on Governmental Relations (COGR) is an association of 188 leading research universities, academic medical centers and independent research institutes. Member institutions play a major role in performing research on behalf of the federal government and other research sponsors. In addition to its focus on the influence of federal regulations, policies, and practices on the performance of research carried out at member institutions, COGR periodically assesses associated institutional policies and processes and provides guidance on effective practices.

In 2014, the National Science Board (NSB) report *Reducing Investigators' Administrative Workload for Federally Funded Research* recommended that institutions "avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so." In 2016, the National Academies Committee on Federal Research Regulations and Reporting Requirements issued the report, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. Among the recommendations included in the report was that research institutions:

- Conduct a review of institutional policies developed to comply with federal regulation of research to determine whether the institution has created additional and unnecessary administrative burden.
- Revise institutional policies that go beyond those necessary and sufficient to comply with federal, state, and local requirements.

In 2016, COGR developed a checklist of actions that institutions have taken to reduce administrative burden, while maintaining oversight and ensuring the stewardship of sponsored research funds. The actions adhere to federal regulations and policy without adopting or extending additional requirements, or otherwise offer the potential to reduce administrative work in a number of areas, including those researchers have identified as being particularly burdensome. Many of the approximately 100 actions put forward have previously been initiated at some of our member institutions with positive effect.

In 2018, we surveyed our members on actions included in the checklist specific to animal research and institutional animal care and use committees (IACUCs), adding several additional items [Appendix A]. Ninety-four of COGR's 188 members (50%) responded to our survey on whether institutions have or were planning to take actions to reduce possible institutional burden in this area. The results of the survey follow (see also Table 1).

We note that the survey was completed by institutional and IACUC administrators and therefore does not capture the perspective of investigators. What administrators and investigators perceive to be burdensome may vary significantly. Both the NSB report cited above and the Federal Demonstration Partnership faculty surveys have indicated that animal research and IACUCs are considered by faculty to be among the areas requiring the greatest administrative work. Institutions can review procedures to identify opportunities to reduce duplicative or unnecessary administrative work.

Results

Protocol Renewals

We asked participating institutions if they have eliminated protocol renewals for non-USDA species and non-DOD protocols for which they are not required. Of the 94 responses received, 47% indicated that their institution has implemented this action. Of the 53% of institutions that have not, 11 institutions (12% of total responses) indicated that they plan to implement it. Among those institutions that have no plans to eliminate these protocol renewals (39 institutions, 41%) rationales included a desire to reduce confusion and potential for non-compliance by holding all protocols to the same standards, and inability to implement this change due to software limitations. Some institutions suggested that they prefer to hold all protocols to the same standards, indicating that it serves as a good form of post-approval monitoring, including adverse events and associated changes to procedures, and that their process for protocol renewal was relatively simple and not burdensome from the institution's perspective.

As many as a dozen institutions suggested that the protocol renewals help them track the number of animals and species used by protocol and investigator; assess minor changes, including personnel changes, locations, and funding sources; and collect other information. A few suggested that their institution was not sure that amendments would accurately and consistently reflect the current protocol.

As annual renewal of non-USDA/non-DOD protocols is not a regulatory requirement, institutions should consider the impact to the research and animal care community and

ensure that these protocol renewals do not increase the time and effort of faculty and staff unnecessarily. Several institutions mentioned using annual renewal of non-USDA/non-DOD protocols for Post-Approval Monitoring. It is important to look at alternative ways of accomplishing this task. Annual renewals increase burden for the IACUC staff, the researcher, and the institution overall. Institutions should make a list of all of their interactions with the PI and evaluate which offer the most value for Post-Approval Monitoring.

Harmonization of federal requirements, through the elimination of the annual review requirement, would lead to institutional change. A report issued by COGR, FASEB, AAMC, and NABR in October 2017, Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden, recommended that USDA "Revise §2.31(d)(5) of the AWA Regulations (AWR) as follows: "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in §2.31(d)(1-4) *at least once every three years*" (emphasis added). A draft report issued by OLAW, USDA, and FDA on December 7, 2018 for a 60 day comment period, *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*, indicates that "USDA will propose, through notice and comment rulemaking, a regulatory change to Title 9 Chapter 1, Subchapter A-Animal Welfare, Section 2.31(d)(5), to remove the requirement that IACUCs conduct "continuing reviews of activities covered by [the Animal Welfare Act] at appropriate intervals . . . but not less than annually," and, instead, insert a requirement that IACUCs conduct a three-year de novo review of activities." In terms of lack of harmonization with DOD, the draft federal report indicates that, "Although outside the scope of 21CCA, Section 2034(d), NIH OLAW, in coordination with USDA, plans to engage with the Department of Defense and the Department of Veterans Affairs about options for harmonizing requirements to reduce administrative burden on investigators who receive support for research with animals from multiple federal agencies."

Pain and Distress Classifications

We asked participants if they have or would consider discontinuing the USDA pain and distress classifications for non-AWA species for which they are not required. Of the 93 institutions that responded, 15% indicated that their institution has discontinued the classifications for non-AWA species. Of those that have not, only 11% indicated that they plan to implement this action.

Seventy-four percent of institutions that have not previously implemented this action indicated that they have no plans to do so citing concerns about animal welfare. Among the comments received, individual respondents suggested that all species should be afforded the same commitment to well-being. A number of institutions suggested that they did not

believe this was burdensome and that having different requirements for different species would be confusing.

Many indicated that it is helpful to review the classifications. Individual institutions indicated that it leads to "procedural discussions and identifies opportunities for technique modifications"; "is important in making determinations of anesthetic/analgesic/recovery needs"; "provides context and consistency"; "keeps things simple"; and serves as a "useful reminder to PIs about pain and distress." Others indicated that it "helps the IACUC triage review procedures" in terms of the category and type of research and how it is reviewed. A few institutions indicated that it is helpful for assessing monitoring and whether monitoring parameters are appropriate for the procedures. A few indicated that their current software does not make this feasible.

Others highlighted other agency or organization requirements or guidance. One institution noted that the DOD also requires use of these categories regardless of species, another that the *Guide* [to the Care and Use of Laboratory Animals] "indicates that IACUCs must consider the potential for pain and distress" and that the USDA categories are one way to meet that requirement. A few suggested that it was required or preferred by AAALAC International.

It is not a regulatory requirement to categorize non-USDA/non-DOD projects into pain categories. There are other ways to account for the ethical/animal welfare decisions that are important to incorporate. If the institution is concerned about tracking unrelieved pain/distress they could consider classifying protocols into 2 categories – those with unrelieved pain/distress and those with no unrelieved pain/distress – 2 categories rather than 4. The current classification for unrelieved pain/distress only accounts for what can be relieved with pharmaceutical agents. A broader definition would be more relevant to the ethical animal welfare consideration.

Use of Designated Member Review

Survey participants were asked if, as the default, their institution implemented designated member review (DMR - which allows one IACUC member designated by the Chair to conduct a review, resulting in a more expedient review) rather than full-committee review (FCR). Of the 94 responses received 66% of institutions indicated that they do use DMR as the default. Of those that indicated that their institution does not use DMR as the default, 3% indicated that their institution plans to implement this action.

Among institutions that do not plan to implement DMR as the default, five indicated that FCR is used for (USDA) category E protocols (pain or distress that will not be alleviated) and three for category D (pain or distress that will be alleviated by IACUC approved methods) or a subset of D (with one indicating that what can go to DMR is generous), and

that defaulting to DMR would not be appropriate. Two institutions indicated that the variety of species and contexts that comprise their program benefit from the full committee review process, and others that the expertise from FCR would be lacking. Some institutions suggested that DMR is used for resolving items identified during FCR, for modifications and category C protocols (no more than momentary or slight pain or distress) or 1- and 3-year renewals, noninvasive teaching protocols, for some amendments, for "simple" protocols, and for annual review of USDA and DOD protocols.

The majority of institutions do incorporate the DMR process as a default. Several institutions stated that they have procedures/policies where certain protocols have to go to FCR. Creating a hierarchy of protocols that require full committee review can be an effective approach and ensure that the most invasive studies are appropriately reviewed. There is also value, however, in having some flexibility to determine what goes to DMR/FCR. Institutions should review their approach to ensure that it is improving animal welfare without creating unnecessary administrative burden. Per the draft federal report on reducing administrative burden for researchers, federal agencies "plan to review and enhance current resources to support IACUC use of existing options that streamline protocol review and significant changes to approved protocols. This includes updated resources to encourage the use of DMR for low-risk activities and for three-year de novo review."

Experimental Details

With respect to reducing IACUC requirements for experimental details that are unrelated to the health and safety of animals, of the 93 institutions that responded to this question, 70% indicated that they have taken this action. Of those that have not, 8% indicated that their institution plans to make this change.

Among the respondents that indicated that their institution does not intend to reduce these requirements many suggested that the additional detail provides a better understanding of the proposed use of animals and whether it is scientifically justified and may help to reduce pain and distress. Some suggested that veterinarians/scientists/IACUC members want to have that detailed information. One institution indicated that this would be a major cultural shift and that there isn't enough information from federal/inspection agencies to support this change.

It is clear that some institutions believe that the additional detail helps them to oversee projects. This may be a false assumption. It is essential that experiments are properly designed and scientifically justified. It is usually not within the expertise of the IACUC members to evaluate the scientific design and validity of the studies. Scientists should be

evaluated as experts in their field and funding by the appropriate agencies/sponsors should be trusted as scientifically justified.

Veterinary Verification and Consultation

We asked survey participants if their institution has adopted OLAW's allowance for expediting protocol amendments via the Veterinary Verification and Consultation (VVC) Process to reduce or eliminate full IACUC involvement. Seventy-seven percent of the 94 institutions responding indicated that they have adopted this process. Of those that have not adopted VVC, 11% indicated that they plan to adopt it.

Among institutions that will not adopt this action, one indicated that it had previously but that faculty used it as a means to seek last minute approval, creating problems for the veterinarian and the investigator; two institutions indicated that the veterinary staff do not want this responsibility or have not expressed interest; two that they have a low volume of submissions or that it would rarely be used; and others that their institution needs to implement programmatic process improvements first or that they don't have time to implement this properly. Two institutions indicated that it is faster/easier to use DMR, and another that this does not seem relevant to their program.

The VVC process was implemented and encouraged by OLAW and agreed to by USDA to support expedited review of procedures that are already agreed to and approved by the IACUC. This is very helpful for most institutions and can decrease the number of significant changes/amendments that the IACUC needs to approve. This does require some work upfront and there are several templates available to accomplish this with minimal effort for a single institution.

Administrative Approval Authority

Survey participants were asked if they have expanded the scope of administrative approval authority by allowing small changes to protocols to be handled administratively, either by IACUC staff or via VVC. Ninety-three percent of institutions indicated that they have. Of those that have not, 5% indicated that they plan to and 2% that they will not, with one institution indicating that "the current workload is not overwhelming." Institutions that state that it does not increase workload should still consider implementation since even for rare occasions expanding the scope of administrative approval authority can be very helpful.

Standardized Protocol Content

Survey participants were asked if they had taken efforts to simplify the IACUC protocol form with standardized language and content requirements. Examples included a

standardized rodent, pre-approved, pre-operative preparation plan and post-operative recovery plan template; a drug-formulary that provides pre-approved dosages, routes and frequency of administration; and use of drop-down lists. Fifty-three percent of institutions indicated that they provide template language. Thirty-seven percent of institutions that responded provide procedural libraries. Forty-eight percent of institutions indicated plans to use standardized language and content.

Of the participants that indicated that their institution does not intend to implement these actions, two indicated that the IO and/or IACUC opposes it; two that there is a lack of consensus on content or the research is too unique for each study; and another suggested that too many drop down lists limits how work is described. Several suggested that the size of their program precludes use of standardized content. Two institutions noted that implementing this change would require an online database which has not yet been implemented, and another that they evaluated online protocols and found drop down menus were time consuming to users (e.g., drug lists containing hundreds of items).

Of the survey participants that indicated that their institutions do plan to implement these actions, plans included online systems to provide templates and standard operating procedures (SOPs), streamlining protocol submission forms and IACUC software, consolidating drug formularies, developing procedural libraries, and integrating standard SOPs into electronic protocol systems. Two institutions indicated that guidance is currently being developed, both noting that it can be difficult to provide SOPs and template language when research is so varied.

Many institutions have implemented the use of template language and many more institutions are pursuing it. As institutions adopt electronic software it is anticipated that this trend will continue as most vendors facilitate the use of standard procedures. Use of standardized procedures across institutions will aid in reproducibility. The Federal Demonstration Partnership is working to provide a standard substances and standard procedures library and broad participation will result in a more robust product. The FDP is also working with OLAW to devise a universal protocol template that could be used by all institutions.

Protocol Documentation

We asked participants if they have replaced required documentation that a proposed protocol was not duplicative with a simple attestation. Sixty-seven percent indicated that their institution has implemented this action. Among those that have not implemented this, 15% indicated that their institution plans to.

Among the institutions that do not plan to use a simple attestation, two suggested that they ask for one sentence and this has not been perceived as burdensome, with one indicating that this is part of the USDA requirement for literature searches. Another institution indicated that they were unaware that the USDA allows this, and still another suggested that the USDA VMO recommended having the question on the protocol form. One institution indicated that they had implemented this, but that a change in software eliminated this and the impact is being evaluated, and another that this would require a change to their form that they are not willing to make at this time. One institution indicated that it wanted to ensure unnecessary duplication of research, and three that this hasn't been discussed but may be in the future.

Documentation that a proposed protocol is not duplicative is not a requirement and there is no clear added value to having the PI address the question in a written format. Institutions that require this documentation felt that this was not an additional burden or that the emphasis was necessary. Since the majority of institutions do have a simple attestation that has been approved by the regulatory agencies, institutions should feel confident that this is not a regulatory requirement. There has never been a requirement for documentation. The USDA requires only a signed assurance. The VA has required it on their form.

Standardized Veterinary Review Procedures

Survey participants were asked if their institution has standardized veterinary review procedures and communications to investigators. Of the 92 institutions that responded to this question 75% have standardized procedures and communications. Among those that do not, 8% of institutions that responded plan to implement this.

Those that do not plan to standardize veterinary review procedures and communications indicated that they have only one or two veterinarians or a consulting veterinarian, or that given their small program the personal attention is worthwhile. One institution indicated that they don't have an (American College of Laboratory Animal Medicine) ACLAM board and that the veterinary reviewer doesn't have training or expertise in lab animal medicine. Two institutions indicated that they haven't discussed this yet but may in the future.

Standardization of veterinary review is most relevant for large institutions with multiple veterinarians. These institutions should consider not only the burden, but the credibility of the veterinary review, if they are continually providing different advice. Admittedly, veterinarians will have different viewpoints and it is important at an institutional level that they determine some common guidelines to provide optimal guidance to their investigators. Standardized veterinary review procedures are more likely to occur where there are SOPs for procedures and drug formularies. Having the veterinary review

performed by a member of the veterinary staff that is/will be responsible for providing veterinary care for the study is also helpful.

Standard Operating Procedures Review

Institutions were asked if they review SOPs on a less frequent basis (e.g., every 2-3 years) based on potential risk (e.g., skill of the investigative team and outcomes of PAM reporting). Of the 93 institutions that responded to this question, 78% have implemented this approach. Of those that have not, 11% indicated that their institution plans to. Among those that do not plan to review SOPs on a less frequent basis, one institution indicated that they re-review all policies within two years; another that they don't have SOPs that require re-review, and two institutions that SOPs are reviewed annually. One institution indicated that it was unclear whether the USDA allowed this.

The requirement is for regular review of standard procedures and policies. The USDA expects the institution to establish a process for review and approval of SOPs and to follow that process. Institutions should evaluate what frequency meets the needs of their program and be consistent. For most polices annually is too frequent and polices should be updated when new information is available regardless.

Animal Numbers

Regarding the action to allow investigators to provide an approximate number or range of animals needed over the course of a research project rather than an exact number, 44% of institutions have taken this action. Of the 53 respondents that replied "no" to this question, 49 responded to our follow-up question on whether their institution plans to implement this action. Of those replying "no", 9 (10% of total responses) indicated that their institution would make this change to allow investigators to provide an approximate number or range of animals.

Among the institutions that indicated that their institution would not implement this action, one indicated that exact numbers are required for reporting and another that they allow investigators to build in a percentage for unexpected outcomes. Two institutions indicated that they have received significant pushback from the USDA on this during inspection, and two noted that if USDA indicated that they allowed this the institution would consider it. One institution suggested that this is difficult to implement with current "Guide" language asking for justification for group sizes.

One institution indicated that they "adhere to the principle of using the smallest number of justified animals necessary to achieve the goals of the study" but that the number of animals can be increased through a simple process amendment, and two that their IO and

IACUC administrator are opposed to use of approximate numbers. Others indicated preference for an exact number or echoed suggestions that to do otherwise would not meet regulatory standards. One institution indicated that this may be raised during implementation of a new system and four that an exact number is required by their current system, with one indicating that an estimate is allowed for breeding colony numbers.

Three institutions suggested that this is not an issue at their institution and that this would not simplify the review process, and three that the numbers are needed given space limitations or linked to their ordering system, with one indicating that they allow use of additional animals based on experimental uncertainty. One suggested that an exact number is needed to track animal usage. Several suggested that the process for increasing the number of animals is not burdensome (e.g., admin review and approval or use of VVC or DMR). Two institutions suggested that investigators simply indicate the high end of a range. Two institutions ask for a maximum number or upper limit and allow for amendments, with requests for a 10% increase subject only to administrative review. One institution suggested that "based on statistical analysis, most studies should have exact numbers" and if extra are needed that can be requested in advance. Others echoed this sentiment with one suggesting that "in order to understand the scientific justification for the numbers, the investigator needs to provide a clear rationale, including such information as group size. We also find that asking for this pushes some PIs to consider their experimental plan more carefully."

There has been a constant flux in the expectation of the IACUCs role in reviewing the animal number justification and statistical analysis to support study design. Depending upon the stage of the study the numbers justification and flexibility required can be significant. Several institutions thought that use of exact numbers was a regulatory requirement or required for reporting purposes. The reporting requirement is for an approximate number of animals and retrospective regarding numbers usage. The prospective number allotment should be flexible. Clarification from OLAW and USDA on these requirements could significantly aid in reducing administrative burden that may be imposed by institutions.

Post-operative Observation Time

We asked if institutions allow investigators to provide a range of time for post-operative observation rather than an exact time (e.g., 4-6 hours instead of every 4 hours) to allow flexibility and avoid findings on deviations from the language where actions were appropriate. Ninety-four percent of institutions indicated that they allow this. Of the six institutions that have not implemented this action, four responded to our follow-up question on whether their institution would allow this. Of those, 2% indicated that they

would with one noting that "the more concerning the endpoints, the less the flexibility" and 2% that their institution would not implement this, with one noting that they are considering it.

Triennial Regulatory Refresher Seminars

We asked if institutions have replaced mandatory triennial regulatory refresher seminars with instructional sessions to streamline protocol writing and review and solicited feedback on how institutions can assist investigators. Of the 92 institutions that responded, 29% indicated that their institution has taken this action. Of the 65 (71%) that responded 'no', 58 responded to our follow-up question on whether their institution would implement this action, with 15% indicating that their institution would and 48% that their institution would not. Many noted that this is a not a federal requirement. The question was in reference to institutional requirements, but the use of the word "mandatory" was confusing and should be omitted from the survey.

Among those indicating that they would not implement this, one institution suggested that this would be too much of a time burden for their IACUC administrator and another that they opposed it, with others indicating that they don't have the resources to carry this out. Two institutions indicated that they will discuss and consider this or that this is evolving and that they constantly solicit feedback; and three that it has not been discussed. Six institutions indicated that they currently do not have/require regulatory refresher seminars, three that it is required every 5 years, another that they find triennial retraining valuable to assure that personnel have exposure to current practices, and two that triennial training is less burdensome with several indicating that it is online. One asked if this recommended action meets the standard for AAALAC accreditation.

The majority of institutions prefer to continue their refresher seminars for triennial reviews with acknowledgement that this is not a regulatory requirement. In instances where there is not a clear regulatory requirement, institutions should consider whether there is an alternative approach that would be equally effective. There is an opportunity to revise this process to focus on the important regulatory components that the PI is responsible for completing. These should include any updates for the PI when institutional policies or regulatory changes occur.

Standardized Models for Training and Documentation

Institutions were asked if they adopt standardized models for training and documentation. Of the 90 institutions that responded, 86% indicated that they have. Of the 13 respondents (14%) that indicated that their institution has not taken this approach, 7% responded that their institution would adopt standardized models. Among institutions that do not plan to

implement this action, some indicated that they develop their own "in-house" training modules; that this is more of a veterinary staff decision; that their institution has standardized training programs for "main activities such as euthanasia, animal handling, [and] aseptic surgery"; that standardized training has not yet been discussed; and that some aspects of training and documentation are standardized while others are specific to the species and research.

Standardized training, in particular on regulation and policy, would allow for optimal cross institutional collaborations and decrease burden. Regulatory agencies could assist by encouraging and providing standardization opportunities for training along with standard templates and protocol formats. Institutions should also take advantage of opportunities for training exchange.

Semiannual Inspections

Survey participants were asked if they use ad hoc consultants in place of IACUC members (e.g., environmental health and safety [EH&S] or physical plant personnel trained to assess facilities) for semiannual inspections of non-USDA species. Forty-five percent of institutions responding to the survey indicated that they do use ad hoc consultants. Of the 52 institutions (55%) that responded 'no', 48 responded to our follow-up question on whether their institution planned to implement this action, with 46% indicating that their institution does not plan to implement this action and 1% that their institution will.

Among those not planning to use ad hoc consultants in place of IACUC members for semiannual review, one institution indicated that they are required to have two voting IACUC members present; several that they feel it is important to engage IACUC members and that there has been no resistance to this; and a number of others that they don't view this as burdensome, and that there hasn't been discussion or a perceived need. One institution only requires one member for non-USDA regulated species, and another uses alternate IACUC members to serve as the second member for inspections. One institution indicated that its IACUC feels it is important to have one IACUC member and that the inspections are also part of the institution's PAM program and a lot of importance placed on the inspections. One institution indicated that it is useful for IACUC members to visit the facilities they oversee and to speak with researchers.

Regarding use of EH&S or physical plant personnel, one institution suggested that EH&S members are not trained to recognize animal pain and distress, and six that their EH&S and facility representatives are IACUC members and that ad hoc consultants would not be well-versed or have the necessary expertise regarding animal welfare and *Guide* requirements. Two indicated that EH&S are invited to attend all IACUC meetings and semi-annual

inspections in addition to IACUC members, with one noting that these units are also severely understaffed.

One institution indicated that USDA regulations require two IACUC members where USDA species are *housed*, one that they may have USDA and non-USDA in the same building and want program consistency, and another suggested that a lack of consistency among USDA and non-USDA species would be more burdensome. One institution indicated that this action would not be consistent with the OLAW assurance, two that this would not be appropriate for their small research program, and three institutions that they utilize consultants in addition to IACUC members, with one indicating that this was suggested by AAALAC.

The majority of institutions do not take advantage of the opportunity to have ad-hoc consultants in place of IACUC members for non-USDA regulated species. This is primarily a burden for the IACUC members and could also impact researchers if scheduling is more difficult due to limited IACUC member availability. Per the draft federal report on reducing administrative burden for researchers, "The PHS Policy allows flexibility in how and by whom the inspections are conducted. NIH OLAW in coordination with USDA plan to develop guidance to address existing flexibilities." The report also notes that "The implementing regulations under Title 9 CFR Section 2.31(c)(3) provide flexibility in allowing the IACUC to determine the best means to conduct program and facility evaluations."

Literature Search for Category D and E Procedures in Non-USDA Species

Regarding eliminating the requirement for a literature search for category D and E procedures for non-USDA species, 24% of respondents indicated that their institution has implemented this. Of the 71 institutions (76%) that responded 'no', 67 responded to our follow-up question on whether their institution plans to implement this action with 62% indicating that their institution would not and 10% of institutions indicating that they would eliminate this requirement.

Among those indicating that their institution would not implement this action, several indicated that use of the same standards provides consistency and reduces confusion and the potential for non-compliance. A number of institutions reported that they have made the decision to treat all species the same way, with one noting that they would not want to have the appearance that the welfare of non-USDA species is less valuable than USDA species. One institution indicated that they disagree with the practice of eliminating this requirement for non-USDA species.

Several institutions suggested that this information is valuable for IACUC review and deliberation. One suggested that this is a simple question that all researchers should

consider when using animals, and others that if there is potential for pain and distress alternatives should be considered regardless of species and that, if alternatives exist, they should be used. Two institutions suggested that it is not burdensome, with one suggesting that investigators are doing this to "stay functional in their domain of science" and another that it is useful to reviewers. A number of institutions indicated this was valuable to the investigator and/or the IACUC and a few that they use it to ensure the three Rs (replacement, reduction, refinement). Several indicated that this would require software changes.

The majority of institutions stated that they would not reconsider requiring literature searches for non-USDA species even with the realization that it is not a requirement. The literature search requirement, similar to the alternatives question, increases burden for our investigators. The perception of burden needs to be directed to the researchers and the majority will state that this is an unnecessary part of the process since they are staying up to date on their field of expertise and are always looking for ways to improve their research. Attestations as to the new models/alternatives are well within their knowledge base.

Literature Search for Category C Procedures Which May Cause Only Momentary Pain or Distress

Participants were also asked if their institution has eliminated the requirement for a literature search for category C procedures for all species. Sixty-two percent of institutions indicated that they have. Of the 36 institutions (38%) that indicated that this has not been eliminated 33 responded to our follow-up question. Of these, 7% indicated that their institution plans to eliminate literature searches for category C procedures and 28% that their institution will not.

Among those indicating that their institution will not eliminate the requirement for a literature search for category C procedures for all species, one indicated that they would not do this for USDA regulated species, others that they don't believe it will save time and that it is useful/valuable for reviewers, and another that a literature search should be performed regardless of pain category. Some institutions indicated that consistency across species is simpler and less burdensome. Others that they want to make sure there are no alternatives to the use of animals or that it is part of the justification for use of animals. One indicated that this is required by regulation and another that they would like to see documentation that this is allowed.

USDA regulations require that the PI consider alternatives to procedures that may cause more than momentary or slight pain or distress. Category C is defined, however, as

procedures causing no pain or distress. USDA might consider providing clarification or education to reduce administrative burden at the institutional level.

On the topic of USDA Policy #12 regarding literature searches, the draft federal report on reducing administrative burden for researchers indicates that "The policy manual was removed from the USDA website in July 2018, and the policies are inoperative, while USDA conducts a review to ensure conformity with the AWA and Animal Welfare Regulations; harmonize with NIH OLAW guidance; and reduce investigator burden where possible. USDA will make any revised and future policies involving the use of animals in research, teaching, testing, experiments, or surgery available for public comment using regulations.gov or a similar service."

Multiple Species and funding Sources in Protocols

We asked if institutions allow investigators the flexibility to include more than one species and funding source per protocol. Of the 92 institutions that responded, 91% do provide this flexibility and 9% indicated that their institution does not. Of the 8 institutions that responded 'no', seven responded to our follow-up question about whether their institution would implement this action. All seven indicated that their institution would not.

Several institutions, including a few that responded 'yes' to this question, indicated that multiple funding sources are allowed but that multiple species are not, while a smaller number indicated that multiples species were allowed but not multiple funding sources. Among the rationales provided were that allowing multiple species would complicate the review or make writing and review more cumbersome; that it would be more confusing when different species have different procedures and care, and difficult to manage from a compliance perspective; and that allowing multiple funding sources makes it difficult for investigators to accurately account for animal related costs and would be more burdensome. One institution suggested that auto-fill allows protocols to easily be replicated and adapted for other species.

Descriptions of Facilities and Husbandry

Institutions were asked if they have eliminated the requirement to describe facilities and husbandry in the protocol if a protocol is using central facilities and centralized staff support. Among the 93 institutions that responded, 86% indicated that they have implemented this. Of those that have not eliminated this action, 12 of the 13 responded to our follow-up question on whether their institution would make this change, with 7% indicating that their institution plans to and 7% that their institution will not. Among those indicating that they will not make this change, three provided comments, with one suggesting that they don' t have centralized facilities, another that they generally don't ask for this, and the third that

they feel it is good practice to describe these activities. Most institutions have implemented this action, and for those that haven't, it isn't clear whether the question is applicable to their institutions.

Protocol Re-write at Triennial Review

Institutions were asked if they do not require a protocol re-write for PHS triennial review if their process allows modifications to be included in the latest version of the protocol rather than as an attachment. Of the 93 institutions that responded, 33% indicated that their institution does not require a protocol re-write for PHS triennial review. Among those that do require a re-write, 13% indicated that they would eliminate this requirement and 52% that their institution would not (two did not respond to this question).

A number of institutions suggested that the protocol could be cut and paste and updated and/or that the system allows the current version of the protocol to be updated and presumably did not view this as burdensome. Some use amendments rather than requiring the researcher to edit the full protocol. Three institutions indicated that they have not considered this and should (with one suggesting that it could slow down the amendment process), two that their systems don't allow it, and one institution indicated that their veterinarian is not on-board. One institution suggested that it would take a lot of staff time to separate out requirements for renewals.

One institution indicated that they value the review of a new protocol at year three as major changes may have occurred, another suggested that "post-approval monitoring can become more complicated if protocol forms are only amended versus being re-written and consolidated" and that a re-write allows the investigator to review the progress of their work. One institution suggested that a re-write "forces changes that have not yet come to light to be exposed," and another indicated that they don't have the ability to include modifications in the latest version of the protocol, rather they are submitted as amendments. Another indicated that the IACUC prepares the draft, based on the previous protocol, for use in renewal. One institution suggested that they require a new submission because many amendments are no longer applicable and another indicated that investigators can resubmit their existing protocol which is assigned a new number.

The PHS Policy does not require a rewrite just a review of what is an ongoing study. There is clear resistance to eliminating the rewrite of a triennial in some format. Institutions may feel that a rewrite is necessary in order to accurately describe in one document what is currently going on. There is value in updating studies. This should be done throughout the life of the protocol, and several institutions have implemented better ways of doing continuing review to improve protocol relevance and applicability. One example is the new

electronic databases that are live documents where amendments are incorporated at the time of approval.

Summary

Where agencies have provided clear mechanisms for risk-based review and alternatives to full committee review many institutions have embraced them. Sixty-six percent of institutions responding use designated member review as the default and an additional 3% of institutions that haven't indicated that they plan to. Seventy-seven percent of institutions indicated that they have adopted NIH OLAW's allowance for "expediting" protocol amendments via VVC. Of those that haven't, 11% indicated that they plan to. The majority of institutions (93%) have also expanded the scope of administrative approval authority by allowing small changes to protocols to be handled administratively by staff or by VVC with 5% indicating that their institution will implement this action.

Most institutions likewise took efforts to employ flexibility and streamline institutional and IACUC processes. The majority of institutions have taken steps to reduce IACUC requirements for experimental details that are unrelated to the health and safety of animals (70%); standardized veterinary review procedures and communications (75%); allowed investigators to provide a range of time for post-op observation (94%); adopted standardized models for training and documentation (86%); allowed more than one species and funding source per protocol (91%); and eliminated the requirement to describe facilities and husbandry in the protocol where central facilities and staff are used (86%).

More than half of institutions defaulted to stricter federal standards out of concern for treating species differently or because of potential confusion and lack of compliance that could result from adopting agency or species-specific requirements, rather than applying consistent requirements across agencies and species. Only 47% of institutions have eliminated annual protocol renewals for non-USDA species and non-DOD protocols; 45% allow use of ad hoc consultants in place of IACUC members for semiannual inspections of non-USDA species; and 44% allow investigators to provide an approximate number or range of animals needed over the course of a research project rather than an exact number. Regarding animal numbers, some institutions indicated that although they recognized that PHS allows for a range, and USDA allows for approximate numbers, DOD does not. Some institutions expressed concern about possible repercussions to adopting proposed actions due to uncertainty in the regulations or federal requirements and past experience with agency inspectors and staff.

Defaulting to the strictest standards was particularly true with respect to assessing pain or distress. Only 15% of institutions reported discontinuing the USDA pain and distress classifications for non-Animal Welfare Act regulated species, expressing concern for animal welfare and providing different levels of protection for some species. A minority of institutions (24%) have eliminated the requirement for a literature search for category D and E procedures for non-USDA species, although 62% have for category C procedures. Institutions reported maintaining stricter/equivalent standards out of concern for animal welfare and scientific integrity, and not due to failure to consider the action and its merits with respect to the potential to reduce unnecessary administrative work.

Conclusions

This survey was targeted to research administrators to determine the extent to which institutions are taking measures to reduce self-imposed administrative burden in their animal care programs. The results revealed that the IACUC and other institutional staff are highly dedicated to oversight and the welfare of animals that are used in research, teaching and testing. Several processes that were implemented weren't required but may fall under the category of best practices providing what is thought to be additional oversight of animals. Other processes, however, may impose unnecessary administrative work, either as a result of differences in federal requirements, uncertainty about federal requirements, lack of resources, including IT resources, or other variables. One variable that can increase administrative burden at the institutional level is isolated difficulties with an investigator. This can lead to a distrust of investigators generally and, following these situations, policies or processes that increase administrative work and affect all researchers.

Institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty. Agencies could provide significant assistance to institutions by distinguishing between requirements and best practices. A contributing factor may be the complexity of multiple sets of regulations, policies, and guidelines that often create confusion. Steps to align agency requirements will help this situation. Additionally, institutions should be confident in their knowledge and understanding of regulations, policies and directives to distinguish between required activities and best practices. In the recent draft federal report on reducing investigator burden, federal agencies indicated their intentions to provide updated resources on what is exempt from IACUC review, to emphasize that guidance is not legally binding unless specific statutory or regulatory requirements are cited, and to "review and develop resources to support IACUCs' use of existing options that streamline protocol review and significant changes to approved protocols without compromising animal welfare" in addition to other measures mentioned in this survey report.

The process of reducing unnecessary administrative work in the oversight of animal research is a shared responsibility. The perspectives of IACUC administrators, researchers, veterinary staff and central administration must all be weighed as an institution considers the requirements that are placed on investigators. While compliance with federal regulations and policies are non-negotiable, institutional interpretations and self-imposed requirements should be thoroughly discussed by all stakeholders. Institutional policies that respect each role in the animal care program can provide high quality animal care, facilitate research, and enhance regulatory compliance while minimizing unnecessary administrative burden on investigators and administrators.

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