

Buffering from Approval to Implementation

Gwen Skladnost, the IACUC Administrator at Great Eastern University (GEU), identified a trend in non-compliance and prepared to bring the matter to the IACUC for discussion as a programmatic concern. Specifically, incomplete survival surgery and post-operative monitoring records were regularly found by IACUC members (e.g., during semi-annual inspections) and veterinarians. In preparation for the IACUC meeting, Skladnost drafted an IACUC policy that reiterated the regulatory expectations and included (a) a new defined template for the records, (b) a mandate requiring use of the defined template, and (c) specific instructions on how to complete the required record.

During the meeting, the IACUC discussed how GEU's IACUC had a robust post-approval monitoring (PAM) program but was suffering from staffing shortages after COVID and was unable to perform

the same rigorous, pre-pandemic PAM. Although the IACUC performed thorough semi-annual inspections, it was clear that something more was needed to ensure adherence to the expectation of maintaining complete surgical and post-operative records.

Skladnost presented the draft policy to the IACUC, proposing that the new template and mandate would address the issue and mitigate the related incidents of non-compliance. The IACUC members engaged in conversation about the proposed policy and came to consensus in favor of the policy; the policy was unanimously approved by the IACUC. After approval, Skladnost lobbied for a roll-out period before the final implementation date; Skladnost was certain that many researchers would not be compliant with the new policy expectations until they were appropriately trained. Accordingly, she asked for a 90-day grace period during which all animal users would be notified of the policy and

trained on the IACUC expectations and the new record template. In other words, full compliance with the policy would only be expected after this 90-day roll-out (i.e., researchers wouldn't be non-compliant until after the 90 days).

Mrs. Maith Coinsias, the unaffiliated member, questioned the roll-out period, and stressed that in addition to new IACUC expectations the policy reiterates specific regulatory requirements. She was concerned that the delayed roll-out may suggest to GEU Principal Investigators (PIs) that maintaining accurate surgical records was not necessary throughout the 90-day roll-out period. She stressed that the policy and additional expectations were intended to focus on an expectation that researchers should already know and reduce non-compliance that can negatively impact animal welfare. She said that as an IACUC, we should be uncomfortable waiting 90 days to expect compliance. Coinsias went on to say that, since the policy was approved today by the IACUC, it should be immediately in effect rather than at 90-days post-approval. Skladnost indicated that she understood, but that it would be difficult to implement a programmatic change without educating the researchers regarding the new expectations. Sceptically, Coinsias agreed and indicated no further concerns.

What are your thoughts:

1. Is Coinsias' concern regarding the IACUCs approving a policy but delaying the implementation date valid?
2. Is Skladnost's logic regarding the delayed implementation date acceptable?
3. Does the IACUC's 90-day roll-out plan meet the regulatory expectation(s)?

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RESPONSE FROM OLAW

The focus of this scenario is when and how should an IACUC policy become actionable. Throughout the *Guide*, it acknowledges the use of institutional and IACUC policies in the oversight of the animal care and use program¹. Of note, the *Guide* emphasizes that for the IACUC to function effectively, a proper environment should be in place to ensure that its policies support animal well-being¹. However, how a policy is employed is not discussed. In this scenario, because the IACUC has approved a new policy created to address ongoing noncompliance, the implementation plan must be promptly enacted and clearly communicated to the researchers. Because the policy is addressing a programmatic issue involving surgical and postoperative recordkeeping, the issue must be reported to OLAW as a serious deviation from the *Guide*^{1,2}. If the IACUC in this scenario finds additional

noncompliance during the phased policy implementation, it is reportable to OLAW. The IACUC should consider a balance between the length and manner of implementation with the risk of additional noncompliance. □

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Plan for Change

Coinsias has good reason to be concerned. As a member of the IACUC, she is responsible for providing continuing oversight of animal activities at Great Eastern University (GEU). GEU's IACUC and veterinarians identified a troubling trend in their program – incomplete surgery and post-operative monitoring records. Per the

*Guide for the Care and Use of Laboratory Animals*¹, successful surgical outcomes are dependent on careful assessment of animal well-being during the surgery and post-operative periods. Maintenance of appropriate records are critical for documenting and tracking the animal's well-being. These records help to ensure (and assure!) that appropriate surgical

procedures are being followed, including the proper provision of anesthesia and analgesia (as required by the U.S. Government Principles², the PHS Policy³, and the Animal Welfare Act⁴). Coinsias' frustration with the research community's lack of familiarity with these regulations, and her desire to swiftly enforce the new policy, is thus understandable.

COMPLIANCE CONSIDERATIONS

The Protocol Review coordinators offer the following compliance considerations:

1. Regulatory requirements regarding IACUC policies and implementation

Although the federal mandates refer to policies as a part of the Animal Care and Use Program (ACUP) [e.g., “The *animal care and use program* (the Program) means the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve the humane care and use of animals in the laboratory and throughout the institution.”¹], there are no specific regulations on the general need for IACUC-approved policies or the manner in which the IACUC/Program develops or implements a policy.

However, OLAW includes reference to specific Program policies in some of their guidance documents, such as:

- (a) “Institutions should have written policies and procedures governing experimentation with hazardous biologic, chemical, and physical agents.”²
- (b) “The specific significant changes described... may be handled administratively according to IACUC-reviewed and -approved policies...”³
- (c) “OLAW expects Assured institutions to have policies and procedures in place that address the care or euthanasia of animals that hatch unexpectedly.”⁴

2. Implications of a delay between IACUC approval and implementation

The impact of the delay depends on the nature of the policy or policy change. IACUC-approved policies represent an expectation of compliance and adherence; that is, the IACUC has voted to establish a programmatic expectation and intends to hold the research team accountable to that expectation (else they be found in

non-compliance with an IACUC-approved policy). It is assumed, although not explicitly stated in federal mandates, that policies are effective as of the date of IACUC approval. Consequently, permitting a delay between IACUC approval and an expectation of compliance can be harmful to the general climate of an ACUP. For example, the delay could invite confusion about programmatic expectations for adherence to policies, e.g., adherence is then construed as at the discretion of the IACUC.

However, if the new or modified policy was based on a change in, for example, the duration of effectiveness of a commonly used analgesic (e.g., buprenorphine⁵), and the update to the policy was to further enhance animal welfare, then how could the IACUC delay implementation knowing that the welfare of the animals would be compromised?

3. Methods to accomplish adequate education, training, and communication

It is not uncommon that a new or modified policy (or other such formal document that establishes a programmatic expectation) requires some amount of education, training, and/or communication to ensure the research community is aware of and understands the expectation(s). Rather than approving the policy before this state of awareness and training has been completed, IACUCs may find it more effective and efficient to do one of two things:

- (a) Determine a future date by which the education, training, and communication can be completed, and post-mark the IACUC approval to that date (e.g., it will take at least 6 months to fully train and educate the research community, so the IACUC policy will take effect in 6 months from the meeting at which it was reviewed).

- (b) Initiate communication, education, and training in preparation for the approval of the policy and then return to the IACUC for approval of the policy once the research team members have been adequately trained.

The IACUC can always revisit the date of approval and adjust as necessary. The ultimate goal is to facilitate compliance and help the research team members completely understand the expectation before they can be held in non-compliance.

However, to permit a circumstance to continue when a policy creation or modification includes an expectation that improves animal welfare conditions (e.g., the newly identified shortened duration of buprenorphine effectiveness⁵) would be a contradiction of the regulatory expectations to minimize pain and distress and the ethical responsibilities and obligations of the IACUC and the institution. Immediate programmatic modifications would be necessary and would not permit a delayed roll-out period. □

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3. NIH/OLAW, *Significant Changes to Animal Activities*. <https://olaw.nih.gov/guidance/significant-changes.htm>
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While Coinsias' concerns are valid, we agree with Skladnost's approach. Successful implementation of a new institutional policy requires time and careful planning. The upcoming change needs to be communicated to GEU's research community, and the community needs to be educated on the new policy and use of the new template. This approach aligns with regulatory expectations. Animal programs have flexibility in how they address deficiencies that are identified, as long as the IACUC defines a reasonable and specific plan and schedule for correcting the deficiency^{3,5}. Skladnost's plan does just that – in partnership with the IACUC, she has developed a new policy reiterating the regulatory requirements around surgery and post-operative monitoring records, a template to support researchers in implementing the expectations outlined in the new policy, and defined a specific timeline in which this transition needs to take place.

Furthermore, we feel that the IACUC's collaborative approach to the implementation of their new policy is admirable. Effective change management requires the institution to consider the individuals that will be impacted, and to formulate an effective communication strategy. Through early outreach and a defined education period prior to implementation, researchers can ask questions, practice, and make mistakes, in an environment that feels collegial and safe. By partnering with the research community during the roll-out process and providing them with the information and the tools that they will need to be successful, they are increasing the odds of effectively implementing the desired change. □

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Acclimation, it's not just for research animals

Mrs. Coinsias is correct that investigators should be familiar with the need for surgical and post-operative records but they will be unfamiliar with the new surgical record template and policy language and may benefit from some additional context. Accurate and complete documentation ensures programs can prove that they are providing adequate veterinary care and are performing procedures as described in approved IACUC protocols. *The Guide for the Care and Use of Laboratory Animals* states that intraoperative and post-operative monitoring should be appropriately documented. Section 2.33(b) (5) of the Animal Welfare Act Regulations (AWAR) lists pre-and post-procedural care as an essential element of adequate veterinary care². While both guiding documents agree that surgical records are important, each program must identify the specific data points used to define “appropriate” and “adequate”. In the absence of a defined template, a program with 100 unique Principal Investigators (PIs) will produce 200 versions of survival surgery and post-operative monitoring records with variations in both content and method (electronic, lab notebook, cage card, or Post-It Note).

Skladnost's initiative defines what elements constitute a complete record and

clarifies how the GEU IACUC expects the information to be documented and maintained. The revised policy, mandated template, and instructions give researchers the tools they need to transform the conceptual expectation into a uniform reality. Skladnost's proposed implementation plan is sound, but she can further alleviate Coinsias' concerns by addressing existing and expanded expectations in the training documentation. She could also highlight the regulatory precedent for delayed implementation and acclimation. OLAW instituted an extended adoption and implementation plan for the 8th edition of *The Guide* in 2012 [NOT-OD-12-020]³. The recent USDA APHIS updates to CFR Parts 1, 2, and 3 concerning standards for birds include a 180-day implementation period for institutions with a current registration⁴.

Reasonable roll-out periods for new or refined policies can accomplish multiple programmatic goals. Delayed implementation supports continuing education and allows for feedback from the research community. These conversations help identify potential non-compliance risks associated with new requirements and allow institutions to develop collaborative solutions or refinements in real time. Sharing the rationale behind a change and communicating the benefits can increase

user buy-in, adoption, and compliance. Engaging the research community during the roll-out period can foster a sense of partnership while avoiding the potential for confrontation or resentment associated with a more abrupt approach. We ask our PIs to incorporate acclimation periods into their protocols to enhance animal welfare. It seems only fair for the IACUC to offer PIs the same consideration. □

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