**Policy, SOP or Guideline? The conundrum of balancing the framework required for a growing animal care program with an overall goal of reducing administrative burden**

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**ABSTRACT**

Problem Statement: For approximately the past 5 years, various organizations have steadily emphasized new measures to reduce both regulatory and administrative burden on investigators and programs using animals in research. The call to reduce regulatory burden was highlighted within the past year, when in March 2018 the NIH released a new Request for Information (RFI) to gather public input in ways to meet Section 2034(d) of the 21st Century Cures Act (enacted December 2016). This RFI was a collaborative effort among the NIH, USDA and FDA, and highlights the ongoing struggle that both federal regulatory agencies and institutions face in reducing administrative burden. Reducing regulatory and administrative burden is a wonderful concept for everyone involved — IACUC members, compliance officers, administrators and investigators all dream about the perfect program, one that runs smoothly where protocols are reviewed and approved quickly to push the boundaries of science both faster and further. On the other hand, a lack of consistent messaging (delivered via policies, SOPs and guidelines) causes varying degrees of confusion and frustration for various members of the program. Thus, animal care and use programs must determine how best to adequately administrate — through the use of policies, specific SOPs and best practices guidelines — to promote and support research while still ensuring programs fulfill the regulatory requirements outlined in the PHS Policy, USDA AWAR and the Guide.

Description of Research: This project describes the processes adopted by a new animal care and use program for identifying topics broad enough to affect the entire program (policies, step-by-step documents that help describe daily and specific activities (SOPs), and recommendations (guidelines) to help facilitate improved communication among the IACUC, compliance and investigators.

**RATIONALE**

Animal care programs are founded on the ethical considerations for the proper care and use of animals, and adhere to a complex set of federal laws, regulations and guidelines. Many programs are bound by institutional documents and/or agreements with regulatory agencies (e.g., PHS Assurance) and may also choose voluntarily to follow the conditions set forth through a secondary accreditation process (e.g., AAALAC). Starting a new program ‘from scratch’ is both a blessing and a curse. On one hand, it allows a program to tailor the administrative documents required to meet the needs; on the other hand, it also requires a program to build everything. Additionally, in today’s climate a new program needs to always consider how best to reduce administrative burden for the entire program.

The WMed animal care and use program started in 2016, and therefore the primary aim of this presentation is to share the WMed laws, regulations and guidelines. Many programs are bound by institutional documents and/or agreements with regulatory agencies to help facilitate improved communication among the IACUC, compliance and investigators.

**STRATEGIES**

The following four strategies become apparent when reviewing the processes outlined by for-profit and non-profit institutions. While developing our internal policies and SOPs, it became apparent that there are strengths and challenges for all these approaches. Perhaps the most important point we recognized is that reducing administrative burden for one branch (e.g., the investigators) oftentimes shifts burden to another branch (e.g., the IACUC) and therefore we aimed to balance the burden. We also recognize there is no ‘one-best approach’ for running a program. The ‘kitchen sink’ approach. Everything is documented in policies and SOPs to increase consistency. This is commonly observed in industry where clients pay contract research organizations for these clearly documented processes.

2. The ‘minimalist’ approach. Only key policies and SOPs are drafted by the institution and investigators. This approach reduces the administrative burden of creating documents, but then shifts onus onto the investigator to submit detailed animal care and use protocols. This approach may also result in ‘gaps’ in the documentation, which requires all parties to consistently revisit approved policies and SOPs for a growing program this is not an issue, as documents are constantly updated to reflect changes in practice.

3. A ‘blended’ approach. This is probably the norm across most of academia and becomes especially apparent when reviewing larger programs that are both PHS-assured and use USDA-regulated species, and/or use wildlife for field studies.

4. The ‘sensitive’ approach. Those programs working with dogs, cats and primates often have additional concerns that require a more comprehensive strategy to ensure the program can confidently meet FOA requests and a potential attack by an activist animal group.

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**MINIMALIST APPROACH**

Documents deemed essential to run a PHS-assured animal care and use program using mice

**POLICIES**

1. Lines of Responsibility
2. Reporting an Unanticipated Problem or Adverse Event
3. Holding Protocol
4. Post Approval Monitoring (PAM)
5. Investigating Animal Care and Use Concerns and Noncompliance
6. Veterinary Verification and Consultation (VVC)
7. Significant Changes in Mouse Numbers
8. Principal Investigator Eligibility
9. Vivarium Visitor Policy
10. IACUC Member Training
11. Assurance of Compliance of Vivarium Standard Operating Procedures
12. Acronyms & Abbreviations
13. Aseptic Technique
14. Biomedical Waste Disposal
15. Transportation of Rodents
16. Handling of Expired
17. Noncompliance
18. Order & Receipt of Animals
19. Personal Protective Equipment
20. Identification Systems
21. Biopsy of Tails
22. Identification Systems
23. Equipment
24. Materials
25. Zoonotic Awareness
26. Housing & Husbandry of Mice
27. Veterinary Assurance
28. Personal Protective Equipment
29. Identification Systems
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119. Identification Systems
120. Biopsy of Tails

**STANDARD OPERATING PROCEDURES**

1. Blood Collection
2. Feed and Bedding
3. Handling Rodents
4. Housing & Husbandry of Mice
5. Zoonotic Awareness
6. 15. Oropharyngeal
7. 16. Rodent Quarantine Procedures
8. 17. Pest Control
19. Mouse Colony Monitoring Program

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**REFERENCES**