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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Problem Statement:
For approximately the past five 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 earlier this 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 polices, specific SOPs and best-practice 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 the research:
This project describes the processes adopted by a new animal and care 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.

Additional Information:
The WMU vivarium received its first animals in August 2016. We describe the challenges that a new program endures while developing all of the necessary documents required to effectively and efficiently administer an animal care and use program using mice as animal models of infectious disease. Animal care and use programs are guided by a complex set of federal laws, regulations and guidelines, and by institutional documents that are created to meet the voluntary accreditation process. Additionally, researchers and technicians are guided by ethical considerations for the proper care and use of animals. As a new and small program, one that developed during this “reductionist” era, we aim to share our unique insights and thoughts into choosing the documents we feel are
absolutely necessary to run a program that uses small non-USDA regulated animals for research. We have taken a very minimalist approach, which has resulted in our program adopting fewer documents than often encountered at other PHS-assured institutions.