Poster Number: 11

Quality Assurance: Committing to Animal Welfare while Reducing Burden
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Problem Statement:
Animal care and use programs are tasked with balancing a dedication to compliance and animal welfare with a commitment to support research activities and reduce regulatory and administrative burden. Many animal care and use programs are employing novel solutions to address specific instances of noncompliance, and more general concerns, such as community disengagement. Common methods include the appointment of compliance officers or post-approval monitoring (PAM) personnel; however, these positions are often perceived by the investigative community as policing forces, as they focus on the identification and penalty of acts of noncompliance, sometimes without regard to the actual impact on animal welfare. These approaches may place too much emphasis on noncompliance as the sole indicator of programmatic success instead of providing opportunities for education and investigator engagement that might better support research goals. The IACUC at the University of Michigan (U-M) has established a program intended to facilitate compliance whilst ensuring that compliance is attainable. The program employs didactic visits in which researchers can openly share concerns, discuss problems with their protocol, and discuss the rules and expectations of the program without threat of consequence provided that there is no immediate threat to animal welfare. Other initiatives of the program aim to encourage collaboration through an investigator advocacy committee, evaluate institutional regulatory burden, identify programmatic vulnerabilities through data collection, and further support researchers by the development of community groups. The Quality Assurance (QA) program is a novel approach within animal care and use regulation that aims to resolve programmatic trends of noncompliance by identifying institutional gaps and weaknesses and cultivating community engagement.

Description of the research:
The U-M QA program has had several phases since its conception in late 2016. Initially staffed with three QA specialists, the first step was to conduct visits with all investigators holding active animal research protocols to identify the current condition of the program and needs of the investigators. The QA specialists review the protocols, identify areas of uncertainty or potential noncompliance with the laboratory, and propose appropriate resolutions. In the event that amendments are necessary, the QA specialist can assist in their initiation as a service to the researchers. The investigators are further engaged in the visit by being invited to share their concerns and questions relating to the ACUP. The QA specialists regularly report trends of noncompliance and PI concerns to the IACUC. A brief second study to evaluate the effectiveness of QA visits in minimizing future noncompliance indicated that they are successful in deterring further occurrences. Additionally, a QA specialist specializing in PI advocacy manages any noncompliant event that results in IACUC sanctions. The PI advocate works
intimately with the investigator and their staff to address concerns identified by the IACUC, assess any other areas of potential noncompliance, and bolster communication between the investigator and compliance staff. With most of the initial visits completed and the team expanded to four QA specialists and an assistant director of QA, the program has progressed to a second phase focusing on the development of community groups and a faculty advocacy committee. Community groups are voluntary opportunities for investigators with common research attributes, such as the use of aquatic species, to connect with each other and discuss collective experiences and concerns. The QA team supports their organization and assists in relaying their feedback and needs to the appropriate parties. The Animal Care & Use Faculty Advocacy Committee (ACU-FAC) is composed primarily of active researchers and is supported by QA staff. They review reports based on QA data collected from QA visits and community groups and propose resolutions to programmatic issues to the IACUC. Future ventures of the U-M QA team include the development of a Laboratory Animal Research Coordinator Certification (LARCC) program to transfer QA responsibilities to specially-trained lab members and further reviews of the program to assess regulatory burden. While these phases are certainly made easier by the existence of a large, dedicated QA team, ideas for smaller initiatives based on QA successes at U-M will be presented.