Quality Assurance: Committing to Animal Welfare while Reducing Burden

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INTRODUCTION

The Institutional Animal Care and Use Committee (IACUC) at the University of Michigan (U-M) has a Quality Assurance (QA) program that resolves programmatic trends of noncompliance by cultivating community engagement and identifying institutional gaps and weaknesses. It additionally aims to educate and empower investigators, increase reciprocity between research, administrative, veterinary and service units, and facilitate compliance whilst ensuring that compliance is attainable. This poster describes a series of phases in which aspects of QA were launched.

PHASE 1: QUALITY ASSURANCE VISITS

QA Specialists conduct didactic visits in which researchers can openly discuss any aspect of the animal care and use program, such as programmatic expectations and obstacles. Additionally, a QA Specialist specializing in PI advocacy provides comprehensive education to investigators and their staff after non-compliant events that result in IACUC sanctions.

Objective of QA Visits
- Increased investigator knowledge of protocol and programmatic expectations
- Researcher input on impediments to the conduct of sound research
- Transition from a practice of auditing animal users and research to mutually instructive discussions

Objective of PI Advocacy
- Collaboration with the investigator and their staff to address concerns identified by the IACUC
- Assessment of laboratory practices for potential noncompliance
- Bolstered communication between the investigator and compliance staff

If noncompliance is identified, it is assessed for:
- Having a potential impact on animal welfare
- Being an individual or programmatic issue
- Ability to be successfully resolved through training and/or protocol revisions

We thank the U-M IACUC and senior leadership for their support in the development of the QA team.

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PHASE 2: PROGRAMMATIC EVALUATION

Through targeted projects, the QA team evaluates institution-caused regulatory burden and identifies programmatic vulnerabilities. Projects may arise from questions and concerns raised in QA visits or from other units of the ACUP.

Examples of Programmatic Evaluation
- Assessment of a regulatory process from start to finish
- Evaluation of the quality and consistency of IACUC reviews
- Regulatory burden analyses of U-M policies and guidelines

Objectives of Community Groups
- Open discussion of experiences and concerns without opposition from animal care groups
- Identification of obstacles to research and ideas for potential programmatic change

Objectives of QA Visits
- Collaborative discussions between laboratory, regulatory, and veterinary staff regarding programmatic practices
- Analysis of QA data, community group concerns, and colleague feedback for trends of regulatory burden
- Recommendation of programmatic changes to the IACUC

QA INVOLVEMENT IN PROGRAMMATIC CHANGE: TUMOR MONITORING RECORDS

IACUC Policy on Surgical and Tumor Monitoring Records
- Tumor monitoring records are required for animals that are being monitored for experimental tumors. These records will be used to ensure that animals are removed from the study at the approved protocol endpoints. Such records must be maintained until the study endpoint for the animal.

Feedback from QA Visits
- Researchers are noncompliant with records expectations, but animals do not exhibit welfare concerns related to tumors, which indicates that appropriate monitoring is occurring.

Risk-Burden Regulatory Assessment
- Requirement of specific form exceeds regulatory expectation for record-keeping.

ACU-FAC Review, Discussion, and Recommendation to IACUC
- “...we consider that the U-M: 1) discontinue the mandate for maintaining written tumor monitoring records; 2) revise the applicable policies and guidelines to reflect the changes; and 3) maintain a current tumor monitoring template that can be utilized at the discretion of the PI.”

PHASE 3: ADVISORY GROUPS

QA-managed advisory groups ensure that the research community plays a collaborative role in the animal care program. Community groups provide 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 Animal Care and Use Faculty Advocacy Committee (ACU-FAC) is a faculty-driven committee that is appointed by the IO. ACU-FAC proposes programmatic change in an effort to reduce regulatory burden.

Objectives of Community Groups
- Identification of obstacles to research and ideas for potential programmatic change
- Open discussion of experiences and concerns without opposition from animal care groups
- Increased investigator knowledge of protocol and programmatic processes

Examples of Programmatic Evaluation
- Increased communication between the research community and animal care groups
- Identification of trends in regulatory burden
- Recommendation of programmatic changes to the IACUC

PHASE 4: LARC PROGRAM

The Laboratory Animal Research Coordinator Certification (LARCC) is awarded to research faculty and staff who complete a 12-week program aimed at providing specific and detailed information concerning the regulations, policies, and procedures governing the use of research animals at the U-M. The Laboratory Animal Research Coordinator (LARC) program is managed by the QA team with didactic sessions led by individuals who are influential to the use of animals in research at the U-M.

Objectives of LARCC
- Education of the research community on the regulations, policies, and procedures dictating the use of animals at the U-M
- Increased communication between the research community and animal care groups
- Provision of certified LARCs with benefits directly related to their training (e.g., ability to approve personnel additions to the protocol)
- Continued collaboration between the QA team and the certified LARC

GUIDANCE FOR QA IMPLEMENTATION

Recommendation Result at U-M
- Make small efforts in QA to encourage great results
  - Trends began to be apparent after first few QA visits, ultimately leading to programmatic changes

- Use early findings to determine future direction of QA program
  - QA visits indicated need for community groups, as field researchers reported many of the same concerns and difficulties

- Ensure program is flexible to accommodate all members of the animal research community
  - Standard visits were not beneficial to PIs with euthanasia-only protocols. A format change (e.g., phone calls, visits via email) improved the QA experience for these investigators.

- Complete an administrative or regulatory process during the visit for benefit to all
  - Assisting with amendments minimizes burden to investigators and reduces review time by having form completed appropriately

- Aim for collaborative partnerships with research community and units of ACUP
  - Investigators reach out earlier and more appropriately when adverse events occur

- Have IACUC and leadership buy-in
  - A common programmatic goal leads to less resistance to change