Risk Assessment and Mitigation by the IACUC

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Objectives

- Risk
- Risk and the IACUC
- Risk Identification
- Risk Classification/Characterization
- Risk Mitigation Strategies
  - aka Risk Control
- Risk Management Cycle
  - Examples
Risk

• “Realization of the potential for undesired and negative consequences of an event”
  • Losses or gains
• Historical - Financial or Project Based
• Regulatory Risk
• Institutional
• Tolerance
  • “Keep us out of the newspapers”
  • “Keep me out of jail”
  • Zero tolerance

Risk and the IACUC

• Why?
• Regulatory Risk
• Financial
• Best Positioned
• IACUC has a responsibility to protect the institution from risks
Risk Identification for the IACUC

- USDA Inspection
  - Negative information available to the public
  - Fines
- AAALAC Site Visit
  - Work required to maintain accreditation
  - CROs – Client perception/reviews
- Client Visit
  - Loss of client work
- PI Procedure
  - Non-compliance or adverse animal outcome
- Reports to USDA and OLAW
  - Negative information available to the public

Sources

- Previous institutional history/experience
- Top areas for deficiencies as noted by USDA, OLAW, and AAALAC
- Regulatory, policy, guideline changes
  - Be in the loop!
    - PRIMR
    - AALAS
    - Listservs
      - OLAW
      - USDA
      - Michigan State
- Metrics from SAFIs, Program Evaluations, PAMs
- Complaints about something never being right
- Process maps (flow charts)
Risk Classification

• Effects resulting from the event occurrence
  • Economic and Non-Economic
    • Economic
      • New systems
      • Additional personnel
    • Non-Economic
      • Reputational
      • Inability to perform research

Risk Characterization

• Severity (Impact) of Possible Adverse Consequences
• Likelihood (Possibility) of Occurrence of Each Consequence
Risk Control & Mitigation

- Avoidance
- Transference/Sharing
- Prevention/Mitigation
- Reduction/Management
- Acceptance

Avoidance

- Decision not to do something based on risk
  - Category E Studies
  - Use of NHPs or other species
  - No Major Multiple Survival Surgeries
  - No USDA work
Transference/Sharing

- Activities will occur but risk is transferred or shared
  - Outsourcing
  - Use of other facilities

Prevention/Mitigation

- Decrease the frequency of an adverse occurrence
  - Policies
  - Training
    - Tip Sheets
  - Post-Approval Monitoring
  - IACUC Requirements
    - Pre-review
    - Veterinary Performance
Risk Reduction/Management

• Assume some level of risk but work to decrease the severity of the potential adverse outcome

• Post-Approval Monitoring

• IACUC Requirements
  • Pilot Studies
  • Veterinary Oversight
    • With or without report back to the IACUC

• Cost/Benefit Analysis
Acceptance

- No actions taken to avoid, prevent, or reduce potential adverse consequences

Risk Management Cycle

- Define Commitment to Risk Management
- Design Risk Management Framework
- Implement Framework
- Monitor Outcomes
- Improve Processes
- Acceptance
- Awareness
Examples

- Risk Control & Mitigation with USDA Changes
- New Risk Program for the IACUC

Risk Management Cycle – USDA Changes

1. Define Commitment to Risk Management
2. Design Risk Management Framework
3. Implement Framework
4. Monitor Outcomes
5. Improve Processes
6. Schedule audits
   - Discuss pre-review process
7. Committed to no NCIs (Prevention)
8. Protocol audits Focused pre-review
Post Approval Monitoring (PAM)

A “Prevention/Mitigation” Program

Objectives

- Program/policy
- Risk determination
  - High risk
  - Medium risk
  - Low risk
- Monitoring
  - Pre-visit activities
  - Visit activities
  - Post visit activities
  - Follow-up
- Reporting
PAM

PAM is a risk based program:
• Proactive focus on education and training
• Identify and correct potential areas of non-compliance
• Provide opportunity for open dialogue
• Flexible
• Frequent assessments of program

Risk Categories

• Non-biased risk factors
• Prior laboratory performance and professional judgement
  • Individual PI’s
  • Research groups
  • Laboratoriest

• Risk categories
  • High risk (High Probability, High Impact)
  • Medium risk (High to Medium Probability, Medium to Low Impact)
  • Low risk (Low Probability, High to Low Impact)
High Risk

- Chronic disease
- USDA category of high risk procedures
- Survival Surgeries with increased potential for complications
- New investigators, species, or disease
- Prior non-compliance concerns
- Requests from animal facility or veterinary staff
- Satellite housing
- Exceptions to the “Guide”
- Exceptions to IACUC policies

Medium Risk

- Non-survival surgeries
- Routine and minimal risk survival surgeries
- Work with biohazards
- Large labs or labs with high turnover
Low Risk

- Euthanasia and tissue collection
- Non-surgical procedures
- Experienced labs with positive findings from past visits and semi-annual inspections

Monitoring Process

Once the risk assessment has been done and the activity has been selected, preparation for the visit will begin.
Advance Activities

• Review protocol and other documentation
• Schedule visit
• Investigator notified of purpose and scope of visit

Monitoring Visit Activities

• Meeting with PI, laboratory manager, other research personnel
• Observation of animal procedures
• Review of relevant documentation
  • Medical records
  • Training records
• Discussion of observations, Q&A
• Significant animal health or welfare concerns are immediately reported to IACUC Director and Attending Veterinarian
Post Visit Activities

• Copies or relevant material discussed during visit are given to the lab
  • SOP’s
  • Policies
  • Educational Materials
• Written report with findings and resolutions sent to the PI

Follow-up Activities

• Follow-up visit to verify resolutions have been successfully implemented
  • Repeated or continued non-compliance result may result in further action
Reporting

- Monthly PAM activities are reported at scheduled full committee meetings

Risk Management Cycle – Risk Program for IACUC

- Define Commitment to Risk Management
- Design Risk Management Framework
- Implement Framework
- Monitor Outcomes
- Improve Processes
- Review policy periodically

Want “Risk-Based PAM” (Reduction)

Define risk levels based on institutional history, tolerance, and regulatory climate

Finalize process, hire personnel, implement process

# Visits for Satellites Reduced

Review policy periodically

Want “Risk-Based PAM” (Reduction)
Conclusions

• Incorporate risk management into protocol deliberations and operations
• Teach IACUC members and staff about the basic tenets of risk management
• Risk management at the local (IACUC) level works