Self-Imposed Regulatory Burden in Animal Research Oversight

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Learning Objectives

- Review why self-imposed regulatory burden is pervasive in animal research oversight
- Identify self-imposed regulatory burden in animal research oversight policies and procedures
- Determine how to decrease or eliminate self-imposed regulatory burden by incorporating appropriate risk mitigation strategies in animal research oversight

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What is Regulatory Burden Vs. Self-Imposed Regulatory Burden

- Regulatory Burden
  - –What you need to do
- Self-Imposed Regulatory Burden
  - –What you do beyond the requirements
  - –Inefficient administrative systems

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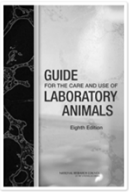
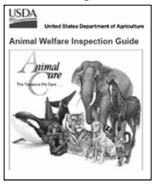
Sources of Regulatory Burden



- Focus on PHS (OLAW) and USDA
- Sources of Guidelines:
  - –*Guide for the Care and Use of Laboratory Animals*
  - –*Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research*
  - –*Occupational Health and Safety in the Care and Use of Research Animals.*
  - –*PHS Policy*
  - –OLAW Articles, Commentaries, FAQs
  - –AWA
  - –AWR
  - –Policies
  - –*Inspection Guide*



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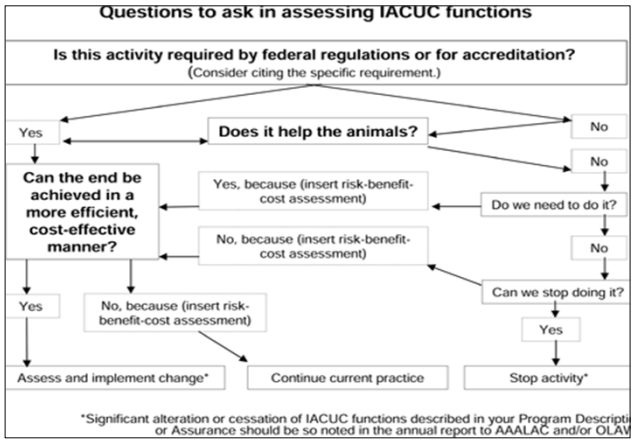
Previous View Point



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OPINION

Decreasing institutionally imposed regulatory burden for animal research

Stacy Pritt[1], Justin A. McNulty[2], Molly Greene[3], Sally Light[3] & Marcy Brown[4]

With the ever-increasing call to reduce self-imposed regulatory and administrative burden in the animal research oversight process, knowledge of the regulations and a desire to streamline policies and procedures are needed to affect a change in culture. In this opinion piece, we provide details on why institutionally imposed regulatory burden can arise.

Initiatives to minimize institutionally imposed regulatory burden have gained traction over the past several years but are not new[1]. While many factors contribute to the proliferation of policies and procedures at institutions desiring to maintain compliance with federal research regulations and guidelines, the current dialog is most likely based on the conflict presented between decreasing research resources stemming from the 'great recession' and its aftermath and an increasing need to balance flexible requirements and risk to the institution.

Regulatory burden is the cost in money, time and effort associated with compliance, where the compliance requirements are established by oversight entities. Institutionally imposed regulatory burden is represented by institutional compliance requirements, policies and procedures that go beyond those established by oversight entities. While animal research oversight by regulatory entities, institutional animal care and use committees (IACUCs), veterinarians, laboratory animal professionals and scientists have tremendously improved animal health and welfare, institutionally imposed regulatory burden can result in additional requirements that provide no advancement for animal health or welfare[2].

The origins of institutionally imposed regulatory burden

Institutionally imposed regulatory burden is a multifaceted problem; it should not be reduced to simple risk aversion or compliance activities without impunity[3]. The regulatory environment in the United States for animal research is notoriously complex but also based on self-governance and flexibility[4,5]. A comprehensive compilation of applicable regulations and guidelines for animal research oversight has recently been published on this matter[4]. But even beyond the laws, regulations, guidelines and reference documents appearing in this most recent publication, a myriad of other directives exist, such as the United States Department of Agriculture (USDA) Animal Care Policies, as well as commentaries found on the National Institutes of Health Office for Laboratory Animal Welfare (OLAW) web site. As a consequence, inexperience or lack of knowledge in this arena can lead to misapplication of the guidelines resulting in institutionally imposed regulatory burden. Individuals tasked with ensuring compliance in a field that has built-in flexibility but also hundreds of nuanced directives, work to fill voids and gaps with rules because they are uncomfortable with the ambiguity and perceived risk. This might explain the desire to apply so-called 'best practices', even when such practices might not be appropriate for a particular institution[3].

Risk aversion has been repeatedly raised as a cause of institutionally imposed regulatory burden[2,3]. Developments such as the USDA's 'Age of Enforcement' in 2010 and new conditions set forth in the 8th edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) have heightened the desire for risk aversion. However, risk aversion is a general term. Individuals or institutions described as 'risk averse' are generally not fully applying the concepts of risk mitigation. Risk management, as a better descriptor, encompasses a variety of strategies based on risk identification and characterization that do not call for more administrative work, but instead work for a targeted approach towards

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Why do we have Self-Imposed Regulatory Burden?

- No One Cause – Multifactorial
- Complex Regulatory Environment
- Inexperience/Lack of Knowledge
- Regulatory Oversight and FOIA Breed Risk Aversion
- Inexperience + Risk Aversion = Lack of Flexibility
  - Also involved is the lack of risk management
- It's the Right Thing To Do

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Why Self-Imposed Regulatory Burden Cont.

- Legacy & Assumptions
  - Regulations/guidelines/standards change
    - Know the regulations/guidelines/standards
  - Institutional systems/programs change
- Protocol Management Systems
  - Are the routing systems correct or overly complex?
  - Do you have to utilize all system options?
- People Dislike Change
  - Lose a sense of control and routine
  - Was the old way wrong?
- Desire to have no SFIs for AAALAC

Don't make assumptions!

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SIAB Paradoxes

- Should be looking at SIAB from a resource perspective
  - –"Nice to haves"
- SIAB diverts resources from direct animal oversight
  - –Resources are limited
- Administrators & PIs get used to inefficient systems and then oppose change
- Many employers discourage the "why" question
- Millennials are process improvement focused

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Examples of Decreased Self-Imposed Regulatory Burden at a Large Academic Medical Center

- Utilize process improvement to decrease SIAB
- Elimination of Annual Reports for non-USDA and non-DoD
- Separate system for personnel additions
- No formal approval letters
- AULs inspected once per year

700+

⇓

100

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Risk Mitigation & Process Improvement

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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

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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 (USDA, OLAW, MSU)
- Metrics from SAFIs, Program Evaluations, PAMs
- Complaints about something never being right
- Process maps (flow charts)

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Risk Classification

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

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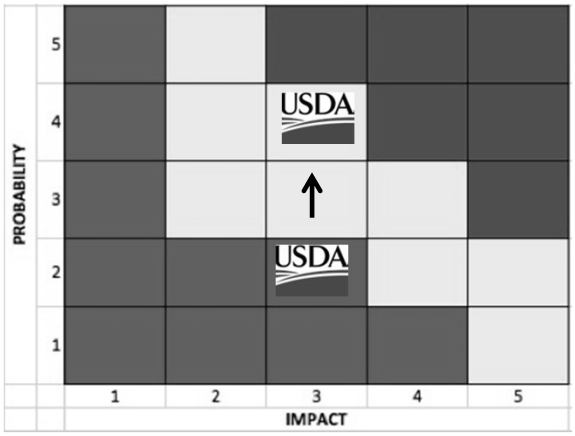
Risk Characterization

- Severity (Impact) of Possible Adverse Consequences
- Likelihood (Possibility) of Occurrence of Each Consequence



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Risk Control & Mitigation

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

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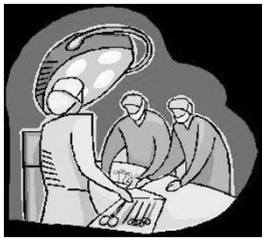
Avoidance (Often Confused with Requirements)

- 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



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Transference/Sharing

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

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Prevention/Mitigation

- Decrease the frequency of an adverse occurrence
  - –Policies
  - –Training
  - –Post-Approval Monitoring
  - –IACUC Requirements
    - –Pre-review
    - –Veterinary Performance

This is where most IACUCs spend most of their time.

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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

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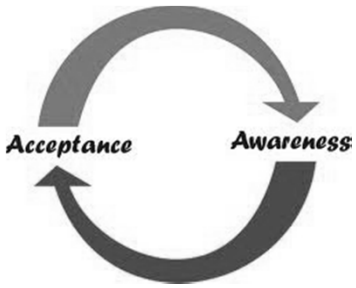
Acceptance

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



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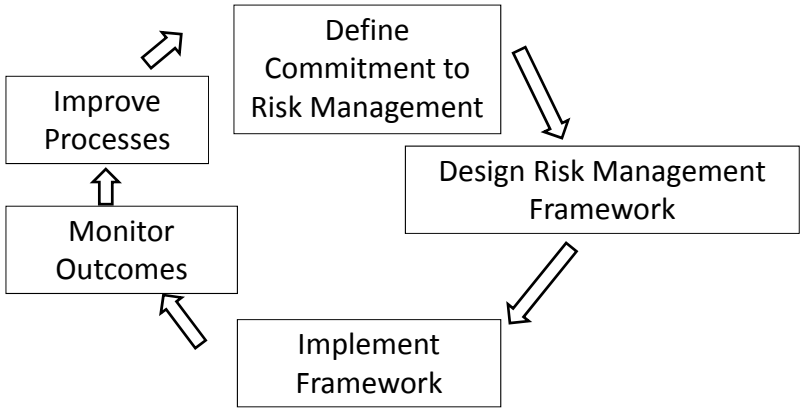
Risk Management Cycle



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Process Improvement

- Identify self-imposed administrative burden
- Systematic evaluation of steps in processes and procedures
- Rarely applied to administrative functions
- Look for easy wins to get started

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Resistance to Process Improvement

- Resistance to Change
- Many accepted/expected processes are actually not required
  - IACUC Legend and Software Systems
- Change in philosophy in the IACUC community
- IACUCs work with multiple stakeholders
- Confusion with Six Sigma
- Lack of employee engagement and training

Process Map – Barrier Points

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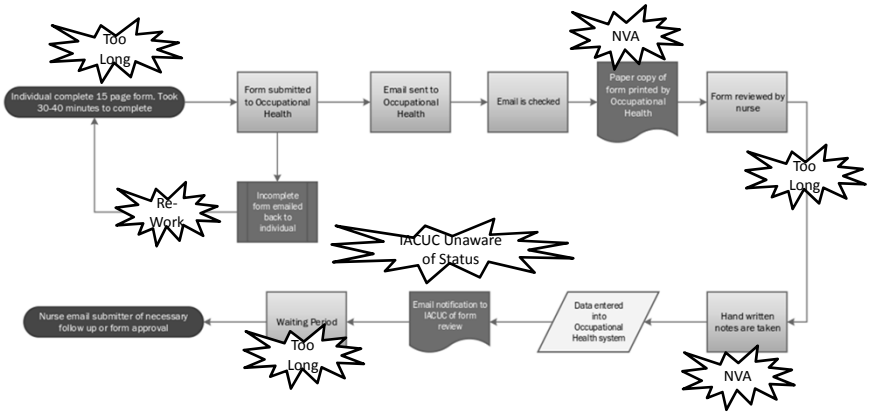

At each step, we asked:

- Is it needed (NVAs)?
- What is wrong (Barriers)?
- Why is it wrong?
- How can it be fixed?

Re-Designed Process Map

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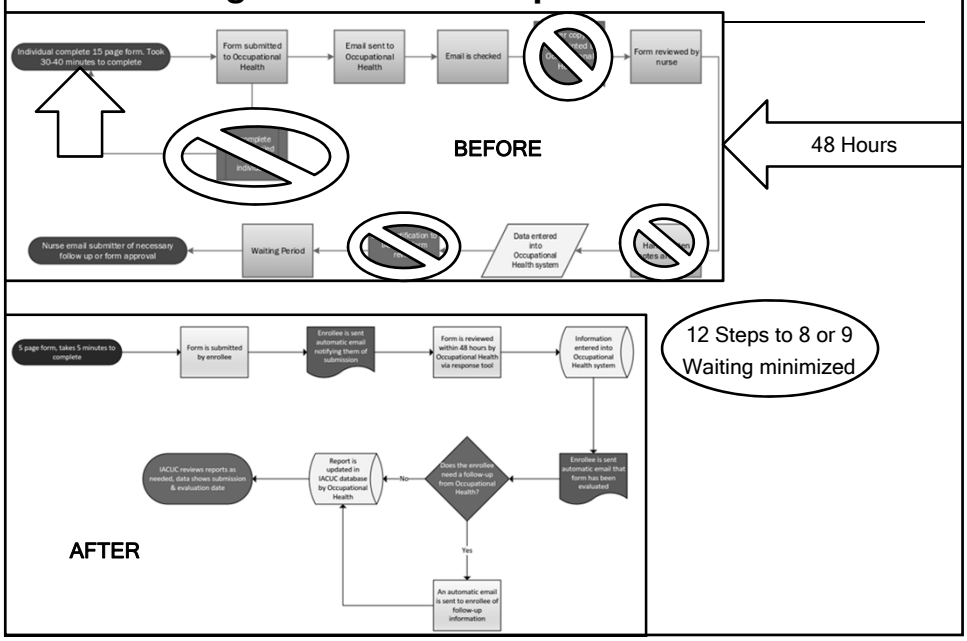

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"Keeping up with the Jones's"