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## Self-Imposed Regulatory Burden in Animal Research Oversight

Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, DACAW  
Director, Institutional Animal Care & Use Committee  
Faculty Associate in Psychiatry (Ethics Division)  
Interim Conflict of Interest Committee Chair & Official

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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

2008 ILAR Journal

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**OPINION**

#### Decreasing institutionally imposed regulatory burden for animal research

By Prof. Anne A. McHugh, M.D. David J. Lippin, M.D. and Robert Brown

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

Regulation in science institutionally imposed rules have become an ever increasing burden on the animal research community. The institutionalized regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence. The regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence. The regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence.

**The origin of institutionally imposed regulatory burden**

Institutionally imposed regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence. The regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence.

**Decreasing institutionally imposed regulatory burden**

Decreasing institutionally imposed regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence. The regulatory burden is a complex web of rules and procedures that have been developed over time and are often not based on scientific evidence.

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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+**

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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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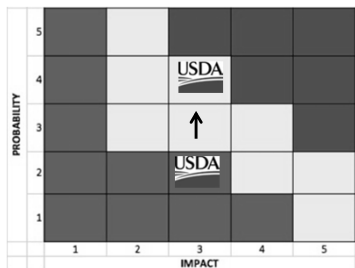
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**Risk Characterization**

- 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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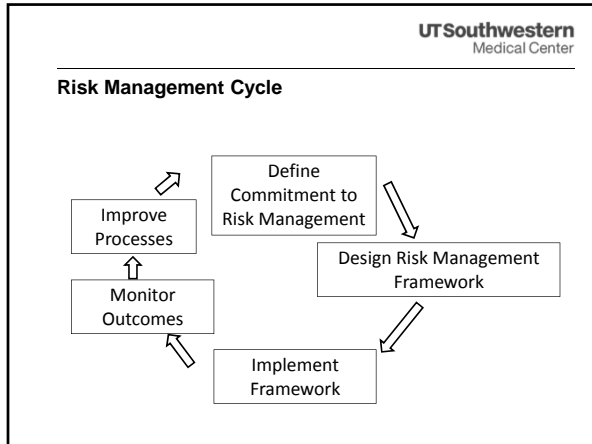
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**Process Improvement**

- 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

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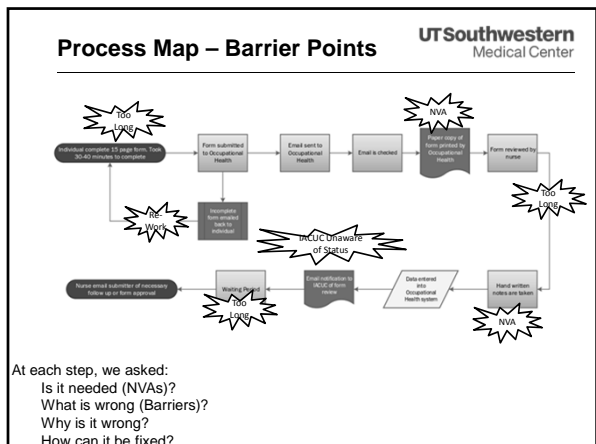
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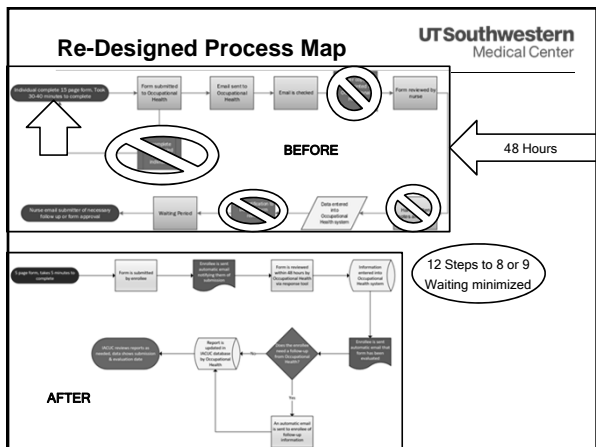
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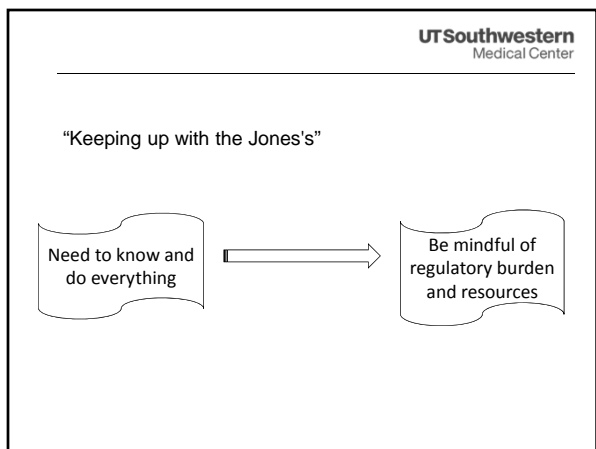
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