Balancing Institutional Risk and Compliance
A Perspective on Regulatory Burden

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Growing Concern...

One emerging area of conflict and tension within institutions is regulatory burden. Investigators are experiencing more and more requirements and institutions are incurring increasing costs.

Is there an appreciable gain in research compliance outcomes?
Administrative and Regulatory Burden can occur when...
“any aspect of Federal legislation, regulation, policy, or Federal/research institution practices that could be made more efficient without diminishing the intended level of protection. Protections could be financial, research subject, safety – broad protections.”


But it is not just efficiency, it is also the effectiveness and breadth of the regulation, policy or guideline.
## Areas of Administrative and Research Oversight

**Administrative**
- Grant and finance administration
- Biosketch requirements
- Conflict of interest
- Clinical billing compliance
- Assurances, certifications and registrations
- Effort reporting
- Progress reports
- Regulatory training
- Subrecipient monitoring
- Personnel management
- Student Mentoring (IDP)
- Record keeping

**Research**
- Animals
- Humans: HIPAA, Data Safety Monitoring
- Radiation
- Biosafety: Select agents, Dual Use
- Human Stem Cells
- Responsible Conduct of Research
- Clinical trials
- New drug/device investigations
- Data management and sharing
- Controlled substances
- Export Controls
- Chemical Safety
- Stem cell research
Cumulative Number of New Federal Regulations or Modifications

Source: COGR presented in FASEB “Sustaining Discovery in the Biological and Medical Sciences”
On average, 42-49% of federally funded research time is spent on administrative tasks. This approximates 15-20% of a faculty member’s time or one day a week!

Are We On An Unsustainable Path?

With expanding regulations, policies and oversight, are we on an unsustainable path where more time and money is spent on administrative and regulatory tasks than on the research itself?
Regulatory Burden
High Level Recommendations

- Focus on the science first in submitting applications.
- Federal oversight system should be critically re-examined.
- Eliminate or modify ineffective regulations.
- Harmonize and streamline requirements.
- Increase University efficiency and effectiveness.
- Create Research Policy Board
“Primary policy forum relating to the regulation of federal research programs...ability and responsibility to make recommendations concerning the conception, development, and harmonization of policies having similar purpose across research funding agencies...”
Recommendations Related to Animal Oversight

• There needs to be a critical examination of regulations, policies, and guidances to ensure that they are efficient while providing the intended level of protection.
  • Research Policy Board

Press Releases, March 31, 2016:

Lipinski Releases Draft of Legislation to Relieve Scientists from Regulatory Burdens that Are Hindering Research at Universities and Labs

Alexander, Murray Introduce Bill to Let NIH "Spend More Time on Life-Saving Treatments and Cures"

LEGISLATION WILL CUT DOWN ON PAPERWORK SOAKING UP 42% OF INVESTIGATORS’ TIME ON RESEARCH GRANTS
Recommendations Related to Animal Oversight

• There needs to be a critical examination of regulations, policies, and guidances to ensure that they are efficient while providing the intended level of protection.
  • Research Policy Board
• Smart harmonization across agencies
  • Ensure workable and streamlined policies and regulations that are consistent across agencies, not just conforming to a set of existing guidances
Agency Harmonization of Regulations and Policies

- Across 13 different agencies, there are 24 different statutes, directives, policies and guiding principles that are used to oversee animal research.
- Two of the documents are common to all agencies: U.S. Government Principles and the Animal Welfare Act.
- The PHS Policy, Guide for the Care and Use of Laboratory Animals, and AVMA Euthanasia Guidelines are applied at 8 agencies.

http://sites.nationalacademies.org/pga/stl/index.htm
Recommendations Related to Animal Oversight

• There needs to be a critical examination of regulations, policies, and guidances to ensure that they are efficient while providing the intended level of protection.
  • Research Policy Board
• Smart harmonization across agencies
  • Ensure workable and streamlined policies and regulations that are consistent across agencies, not just conforming to a set of existing guidances
• Streamline assurances and reporting
  • What do funding and regulatory agencies need to know to be assured that the care and use of animals by investigators and institutions meets necessary standards.
Institutional and Investigator Assurances for Animal Research

Institution

- IACUC Approval
- Annual Protocol Review
- Modifications and Amendments
- Triennial Review
- Unanticipated Events

Investigator

- Post-Approval Monitoring by IACUC
- Comparison of Grants and Protocols

NIH

- PHS Assurance
- Annual Report
- Non-Compliance Reports
- AAALAC accreditation
- Suspension of protocol
- Subcontracts

- Vertebrate Animal Section (SF 424)
- Terms and Conditions of Grants
Recommendations Related to Animal Oversight

• There needs to be a critical examination of regulations, policies, and guidances to ensure that they are efficient while providing the intended level of protection.
  • Research Policy Board
• Smart harmonization across agencies
  • Ensure workable and streamlined policies and regulations that are consistent across agencies, not just conforming to a set of existing guidances
• Streamline assurances and reporting
  • What do funding and regulatory agencies need to know to be assured that the care and use of animals by investigators and institutions meets necessary standards
• Self-imposed burden is significant and must be addressed
Self-Assessment

Questions to ask in assessing IACUC functions

Is this activity required by federal regulations or for accreditation?  
(Consider citing the specific requirement.)

Yes

Does it help the animals?  

No

Can the end be achieved in a more efficient, cost-effective manner?  

Yes

No, because (insert risk-benefit-cost assessment)

No

Do we need to do it?

Yes

Can we stop doing it?

Yes

No

Continue current practice

Stop activity*

No

No

*Significant alteration or cessation of IACUC functions described in your Program Description or Assurance should be so noted in the annual report to AAALAC and/or OLAW.
We Are Making Progress

• Congress is drafting legislation
  • House and Senate bills drafted

• Agencies are listening
  • Policies have been instituted to help reduce burden (Veterinary Verification and Consultation Process)
  • Harmonization has occurred

• Institutions are starting to move
  • Advisory Boards
  • Some institutions analyzing their administrative and regulatory burden

But, we still have much to do before we are successful
Looking Forward:
We are at a Fork in the Road

• We can change the way we think about regulatory oversight, or we can continue on an unsustainable path.

• The scientific community can make a difference.

• We have a window of opportunity while there is momentum for us all to come together to address the ever expanding problem of administrative and regulatory burden. It is on each of us to ensure that this gets done!
A Special Thanks...

to Molly Greene, BA, CPIA who helped develop and refine some of the concepts presented.
Self-Imposed Burden

FDP Survey

- IACUC and IRB requirements were the most time intensive regulatory activities
- The main activities taking investigators away from research were:
  - Preparing IACUC protocols
  - Completing annual and triennial reviews
  - Making protocol revisions

Table 16. Estimated Mean Time Taken Away from Research by Responsibility Subcategories of IACUC/Animal Subjects for Survey Respondents with Substantial Workload in This Area

<table>
<thead>
<tr>
<th>Responsibility Subcategory</th>
<th>Mean Time Taken from Research (1= None, 5= Very Much)</th>
<th>% with Substantial Workload</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing IACUC protocols for initial review</td>
<td>3.62</td>
<td>90%</td>
</tr>
<tr>
<td>Completing annual IACUC reviews and three-year re-writes of protocols</td>
<td>3.38</td>
<td>82%</td>
</tr>
<tr>
<td>Completing protocol revisions requested by reviewers</td>
<td>3.29</td>
<td>78%</td>
</tr>
<tr>
<td>Fulfilling federal requirements for training in animal care and use</td>
<td>2.75</td>
<td>56%</td>
</tr>
<tr>
<td>Satisfying federal requirements for funded projects (e.g., tracking animal numbers)</td>
<td>2.63</td>
<td>51%</td>
</tr>
<tr>
<td>Maintaining veterinary medical records</td>
<td>2.25</td>
<td>38%</td>
</tr>
</tbody>
</table>
## IACUC-Admin Listserv Survey of Regulatory Burden

<table>
<thead>
<tr>
<th>Number Protocols</th>
<th>Number Institutions</th>
<th>% Full Committee</th>
<th>% Amendments Full Committee</th>
<th>% VVC Amendment Review</th>
<th>% Annual Review All Protocols</th>
<th>Person hours/year in IACUC meetings</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100</td>
<td>15</td>
<td>52.4</td>
<td>52.1</td>
<td>40.0</td>
<td>100.0</td>
<td>209.1</td>
</tr>
<tr>
<td>101 - 300</td>
<td>19</td>
<td>41.3</td>
<td>64.4</td>
<td>57.9</td>
<td>84.2</td>
<td>271.0</td>
</tr>
<tr>
<td>301 - 500</td>
<td>17</td>
<td>51.0</td>
<td>57.3</td>
<td>41.2</td>
<td>70.6</td>
<td>496.2</td>
</tr>
<tr>
<td>&gt;500</td>
<td>13</td>
<td>47.7</td>
<td>62.8</td>
<td>53.8</td>
<td>53.8</td>
<td>830.5</td>
</tr>
</tbody>
</table>

- 41-52% of institutions require Full Committee Review of all protocols
- 51-64% of Amendments/Modifications are reviewed by Full Committee
- 40-58% of institutions use Veterinary Verification and Consultation
- 54-100% of institutions perform Annual Review of all protocols