Regulatory Burden and Research at Michigan State University

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Why Do We Have Regulatory Oversight of Research?

- Financial investment of the federal government and other agencies
- Accountability and transparency
- Protection of research subjects, investigators and institutions
- Public demand

- The Age of Enforcement = The Stakes are high!
What Is The Regulatory Process?

- Law is passed
- Regulations developed by state/federal agencies
- Comment Period, Review, Published
- Interpretation by Institutions
- Agency clarification of policies, guidelines and FAQs
What Regulations Affect MSU Research?

Regulations that relate to:

• Financial management
• Chemicals
• Human subjects
• Animal subjects
• Radioactivity
• Recombinant DNA
• Research misconduct
• FDA drugs & devices

• Export controls
• Conflict of interest
• Environmental emissions
• Subcontract oversight
• Embryonic stem cells
• Wildlife research
• Responsible conduct of research
• Etc, etc, etc
Regulatory Burden and University Research – What has been done?

• Rand Report
  – One of fastest rising costs to research universities

• NIH Regulatory Burden Study - 1998
  – Animal Care, Human Research Protection and Hazardous Substances

• Federal Demonstration Partnership
  – Faculty Survey: 42% of time spent on federally funded research is associated with administration
What Is Happening Nationally Now?

- National Research Council Committee on Research Universities
  - Challenges to the research university
- Federal Demonstration Partnership
  - Development of tools and projects
- Association American Universities (AAU), Council on Government Relations (COGR), and Association of Public and Land-grant Universities (APLU)
  - Recommendations to the NRC Committee
- Conversation about raising 26% cap on administrative costs
What Is Happening at MSU?

- Research oversight is a shared responsibility between administration and faculty
  - Personal responsibility to ‘do the right thing’
  - Faculty committees for many areas of oversight
- Education, training and tracking
  - Best way of minimizing burden
- Accreditation programs (AAHRPP and AAALAC)
  - “Gold standard” to the public
What Is Happening at MSU?

• Excellent staff that have obtained an operational understanding of regulations, policies, guidelines, FAQs, etc to interpret federal directions and mandates
  – Considerable discussion of regulations and issues
• Post-approval monitoring of research
  – Effective way to reinforce education and fix problems
• Increase in research and complexity of research
  – Bigger, cross-institutional grants
Efforts to Reduce Burden at MSU?

• Human Research Protection Program
  – Demonstration project to provide 2 year approvals for non-federal, low risk, expedited protocols
  – Shortened application for exempt protocols

• Animal Care Program
  – Animal Use Form streamlined (literature search)
  – Online ordering of animals to be launched soon

• Environmental Health and Safety
  – Electronic templates for SOPs
  – Online Biosafety form
# Increased Number of Regulatory Protocols Reviewed

<table>
<thead>
<tr>
<th>Regulatory Unit</th>
<th>Number of Protocols 2007</th>
<th>Number of Protocols 2010</th>
<th>% Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Institutional Review Boards</td>
<td>3639</td>
<td>4531</td>
<td>24.5%</td>
</tr>
<tr>
<td>Institutional Animal Care and Use Committee</td>
<td>650</td>
<td>898</td>
<td>38.2%</td>
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Shaping the Future

- Kuali Research Administration integrated software
- CIC inter-institutional reliance and reciprocity agreements
- Other ideas?