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?