

Regulatory Burden and Research at Michigan State University

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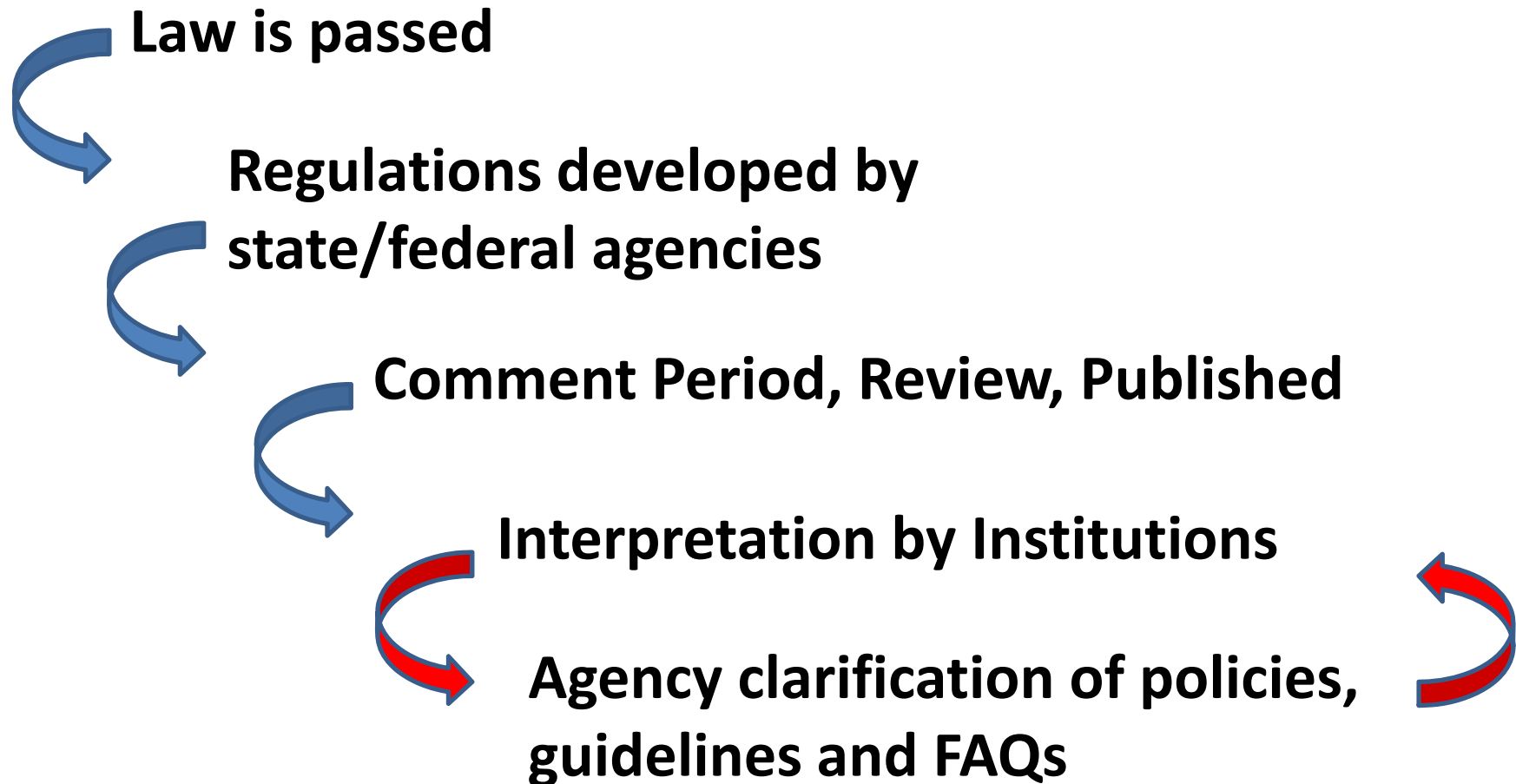
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Why Do We Have Regulatory Oversight of Research?

- **Financial investment of the federal government and other agencies**
 - **Accountability and transparency**
 - **Protection of research subjects, investigators and institutions**
 - **Public demand**
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- **The Age of Enforcement = The Stakes are high!**

What Is The Regulatory Process?



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

Regulatory Unit	Number of Protocols 2007	Number of Protocols 2010	% Increase
All Institutional Review Boards	3639	4531	24.5%
Institutional Animal Care and Use Committee	650	898	38.2%

Shaping the Future

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