

From Chaos to Control: How Mayo Clinic Reformed After DOJ Investigation

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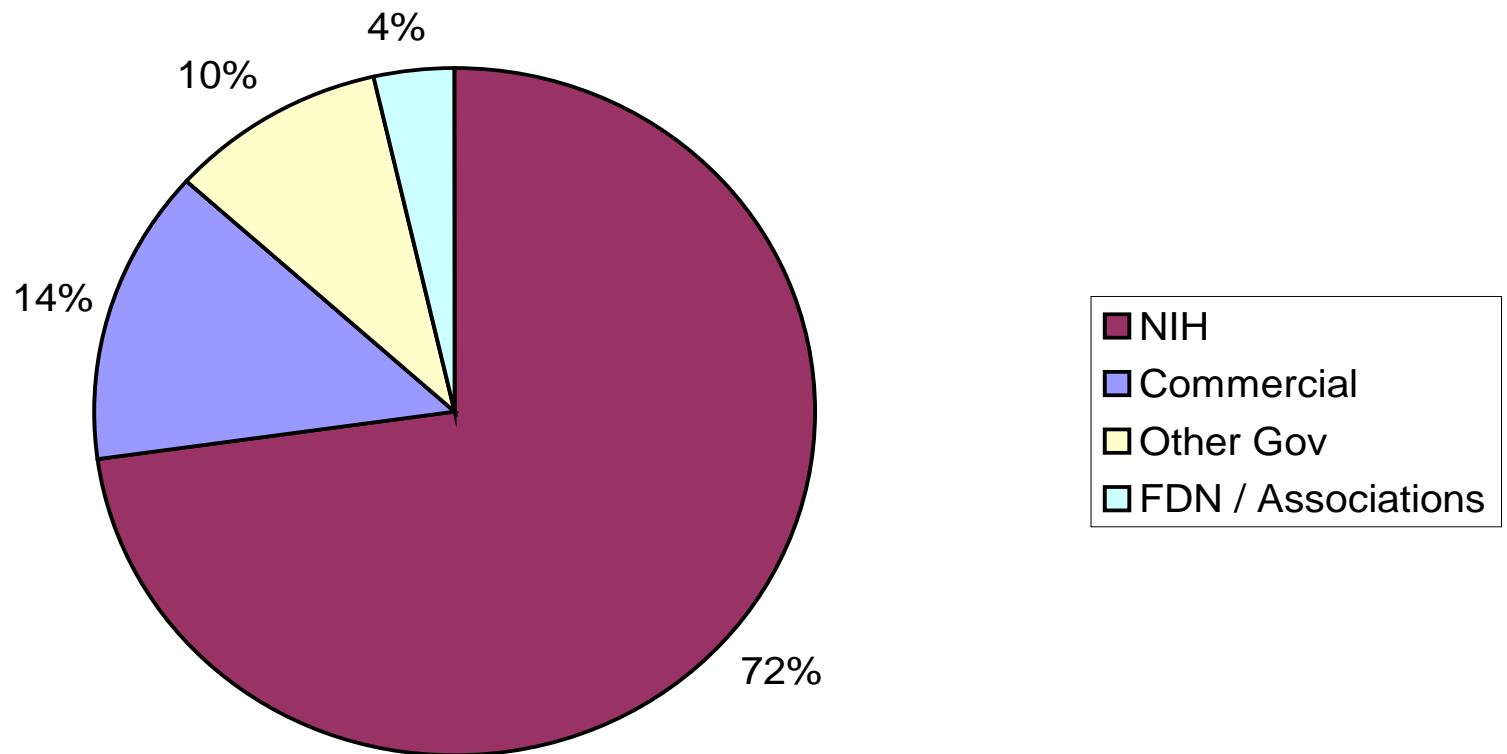
NCURA Region IV 2011 Spring Meeting

Research at Mayo Clinic

- Individuals working in research >6,000
- Total peer-reviewed citations >4,000
- Research space in sq ft >825,000
- Total active human studies >8,000
- Grants and contracts >2,800
- In top 20 NIH funded AMC's



2010 Revenue by Funding Source





Sources of Research Funding*

Extramural

- National Institutes of Health (NIH)
- Other Government Agencies
 - Dept of Defense
 - NSF
 - State
- Industry/Commercial
- Non-Profit Agencies

60%

\$343M

Intramural

- Income from Operations
- Development
 - Endowment Return
 - Operations Fundraising
- Royalty Sharing

40%

\$211M

Top Ten Sources of NIH Funding by Institute / Center

Awarded dollars per NIH by NIH fiscal year - excluding ARRA funding

	2010
1. National Cancer Institute (NCI)	\$ 65,265,815
2. National Inst of Diabetes and Digestive and Kidney Diseases (NIDDK)	\$ 30,475,778
3. National Heart, Lung and Blood Institute (NHLBI)	\$ 22,113,967
4. National Institute on Aging (NIA)	\$ 14,638,261
5. National Center for Research Resources (NCRR)	\$ 14,532,999
6. National Institute of Neurological Disorders and Stroke (NINDS)	\$ 11,750,186
7. National Institute of Allergy and Infectious Diseases (NIAID)	\$ 8,882,779
8. National Institute of General Medical Sciences (NIGMS)	\$ 7,795,102
9. Nat'l Inst of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	\$ 7,011,240
10. National Eye Institute (NEI)	\$ 2,303,868



Research Finance at Mayo Clinic

- **Handles, for all award types, all post award finance activities including:**
 - **Filing FSRs and other sponsor reports, invoicing and cash draws, all compliance monitoring, disbursements, labor distribution and effort reporting, meeting with PIs, etc.**
 - **Also handles management reporting for overall Research function at Mayo**
- **Organizationally part of the Finance Department at Mayo Clinic**
- **Staffing numbers for Research Finance**
 - **Pre DOJ investigation-2003-approx 25 FTEs**
 - **Post implementation of controls-2008-approx 100 FTEs**

DOJ Investigation

- **Whistleblower (qui tam) suit filed by former Mayo Research Finance employee in 2003**
- **DOJ review included NIH research funds received and spent at Mayo from 1992 to 2003**
- **DOJ review focused on cost transfers and overall documentation of charges on NIH awards**

Settlement & Transition

- In May 2005, while admitting no wrong doing, Mayo agreed to settle for \$6.5 million
- DOJ issued a press release and the investigation was closed
- In June 2005, NIH sent a letter to Mayo asking for compliance related information and assurances

NIH Inquiry

NIH raised compliance related questions in four distinct areas:

- **Cost Transfers**

- How does Mayo ensure cost transfers are:
 - allowable and allocable to the NIH grant?
 - not made to cover cost overruns?
- What systems does Mayo have to detect accounting errors and identify cost transfers?

- **Financial Management Systems**

How does Mayo ensure:

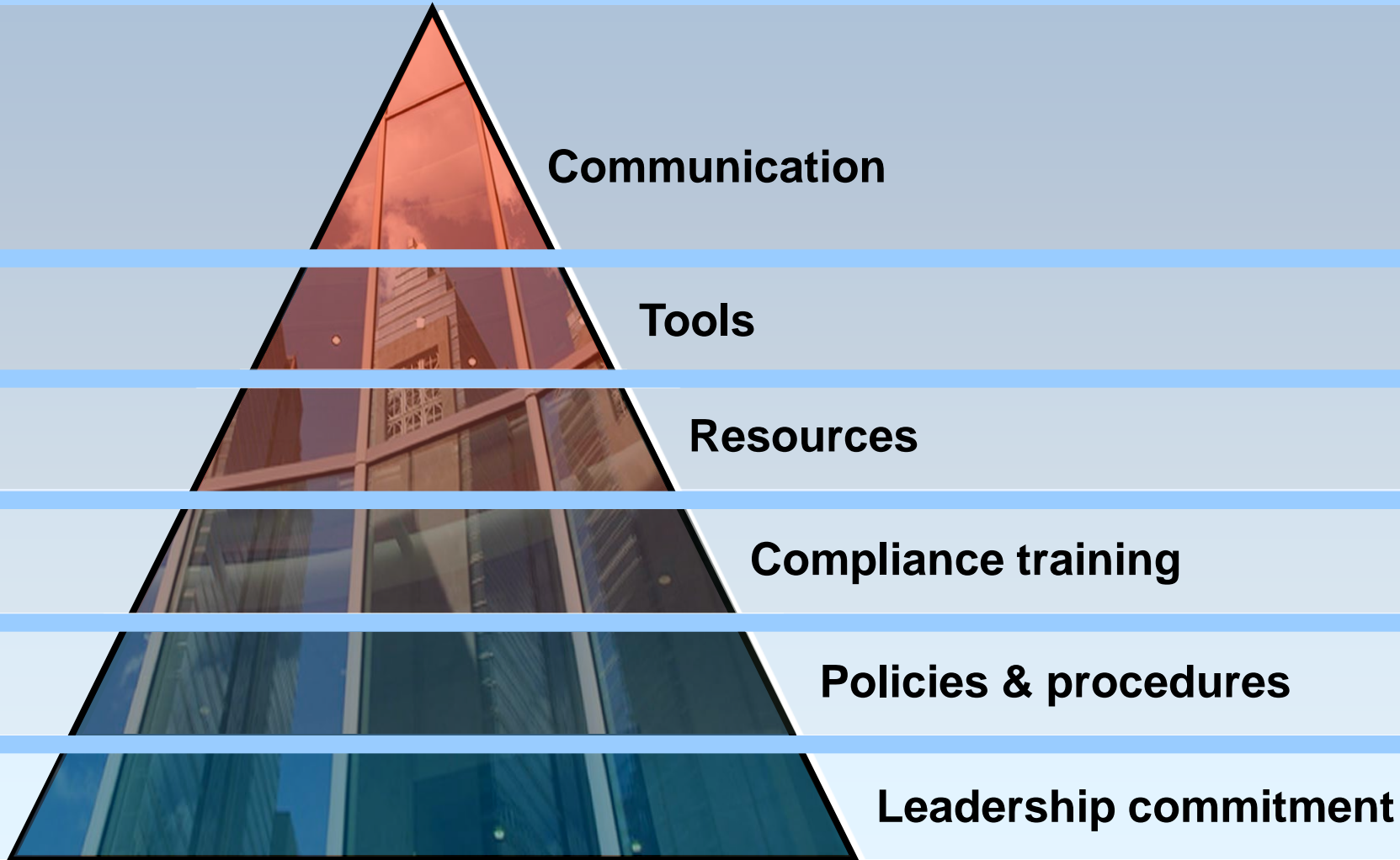
- all charges to NIH grants are supported by complete and verifiable documentation?
- compliance with terms and conditions of NIH?
- NIH grant funds are used solely for authorized purposes?

NIH Inquiry (continued)

- **Written Policies and Procedures**
 - How does Mayo ensure compliance with its policies?
 - What process does Mayo have to ensure that policies are accurate and remain current?
 - How are policy requirements communicated to individuals who have a role in the conduct and administration of NIH grants?
- **Roles, Responsibilities, and Training**
 - Are fiscal, scientific, and administrative responsibilities clearly stated in Mayo's policies?
 - Are oversight responsibilities assigned in policy documents?
 - What training does Mayo provide to both new and existing faculty and staff?



Framework to Define Compliance Infrastructure



Mayo Response (2005- 2007)

- **Initiatives included several projects to examine our compliance in key areas**
 - **K Awards**
 - **Cost Sharing**
 - **Direct vs. indirect cost treatment**
 - **Unlike Circumstances**
- **Identified add'l compliance issues, self-disclosed to NIH**
- **Implemented new ERP system, including Grants Management**



Continued Maturation of Framework

- **In 2008, adopted Quality Management System, modeled after ISO framework**
- **Cornerstones remain; adds continuous improvement and customer satisfaction elements**



Current Framework to Define Compliance Infrastructure





**Continuous
Improvement**

**Management
Commitment
*START***

Culture

**Customer Service
& Satisfaction**

**Quality
Management System
Elements – Putting
the Pieces Together**

**QMS
Administration**

**Measurement
& Analysis**

**Competence,
Awareness,
& Training**

**Documentation
System**





Research Finance Mission Statement

Mayo Clinic Research Finance believes in quality management. Research Finance aspires to use quality as the vehicle behind all it does in an effort to meet and exceed our customers' expectations. The Research Finance Quality Management System emphasizes a proactive approach to meeting our customers' needs and to ensuring continuous improvement.







QMS Administration



QMS Annual Quality Plan Goals

- Maintain a culture that ensures **all employees are empowered** to play an integral role in the continuous improvement of the operation and recognize them for their contributions
- Create value for our customers and increase our understanding of our **customers' needs**
- Sustain established quality levels while implementing additional **quality improvement projects and strategies**
- Continue to **identify opportunities** to gain efficiencies through the improvement of core business processes









Financial Status Report Summary

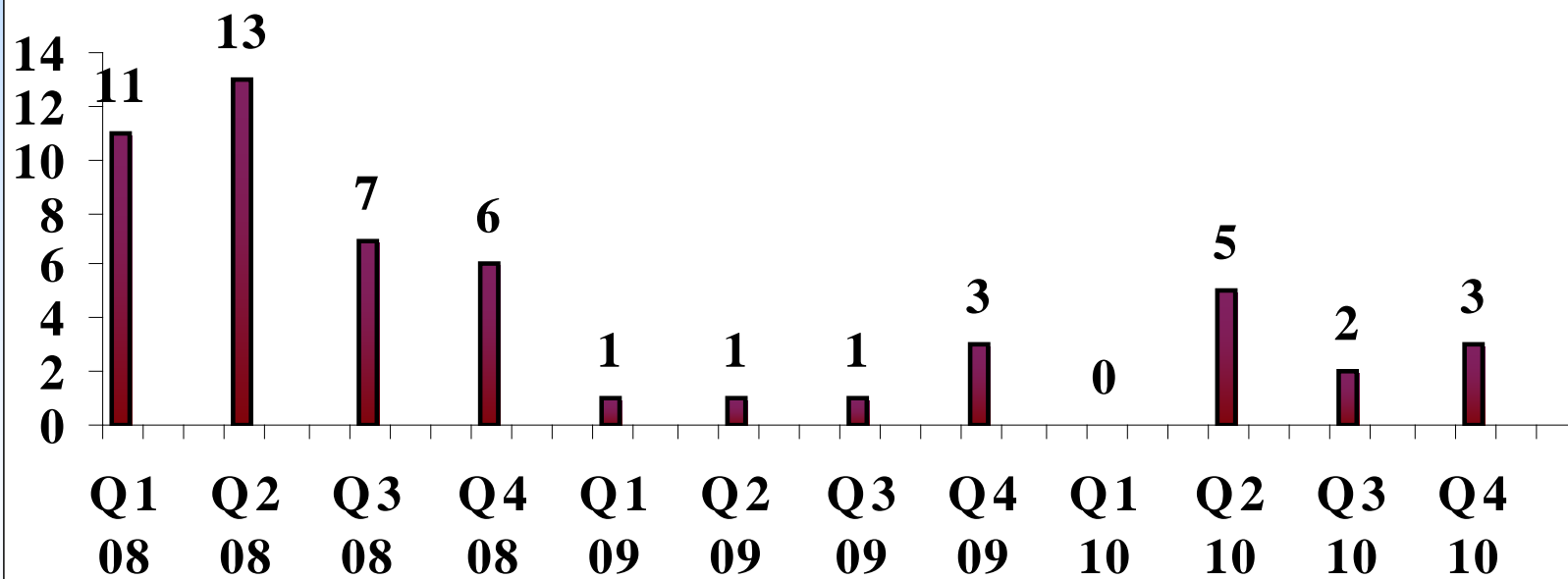
	Completed on Time in Current Period				Complete From Prior Period		
	# Due	# Complete	# Late	%Complete	# Revised	# late External	Days Late
January	3	3	0	100%	0	0	0
February	5	5	0	100%	3	0	0
March	8	8	0	100%	1	0	0
April	7	7	0	100%	1	0	0
May	9	8	1	89%	0	0	0
June	23	23	0	100%	1	0	62
July	16	15	1	94%	0	0	0
August	10	10	0	100%	0	0	2
September	38	38	0	100%	1	0	0
October	27	27	0	100%	0	0	0
November	27	27	0	100%	1	0	0
December	35	35	0	100%	2	0	0
Total YTD 2010	208	206	2	99.0%	10	0	
Total 2009	162	161	1	99.4%	11	4	

Federal Grant Review Summary

	6-Month Reviews			9-Month Reviews			12-Month Reviews			14-Month Reviews	
	Total Reviews Due	% Completed On Time		Total Reviews Due	% Completed On Time		Total Reviews Due	% Completed On Time		Total Reviews Due	% Completed On Time
		Associate	Specialist		Associate	Specialist		Associate	Specialist		Specialist
Jan	184	99%	100%	65	100%	100%	39	100%	100%	1	100%
Feb	82	100%	98%	0	100%	100%	35	100%	100%	7	86%
Mar	135	95%	100%	0	100%	100%	65	100%	100%	17	100%
Apr	1	100%	100%	0	100%	100%	69	100%	99%	14	100%
May	0	100%	100%	0	100%	100%	43	100%	100%	42	100%
June	17	100%	100%	0	100%	100%	58	95%	98%	21	100%
July	34	100%	100%	0	100%	100%	194	92%	100%	16	94%
Aug	35	100%	97%	0	100%	100%	82	96%	99%	17	100%
Sept	70	100%	96%	0	100%	100%	143	99%	81%	157	91%
Oct	53	100%	100%	0	100%	100%	8	100%	100%	42	74%
Nov	43	100%	86%	0	100%	100%	1	100%	100%	84	88%
Dec	59	100%		0	100%	100%	19	95%	89%	3	67%

Performance Reviews Past Due Goal: 0

■ Reviews Past Due









**Does it
Work?**





Indicators of Success

$$\text{Quality} = \frac{\text{Service and Outcomes}}{\text{Cost}}$$

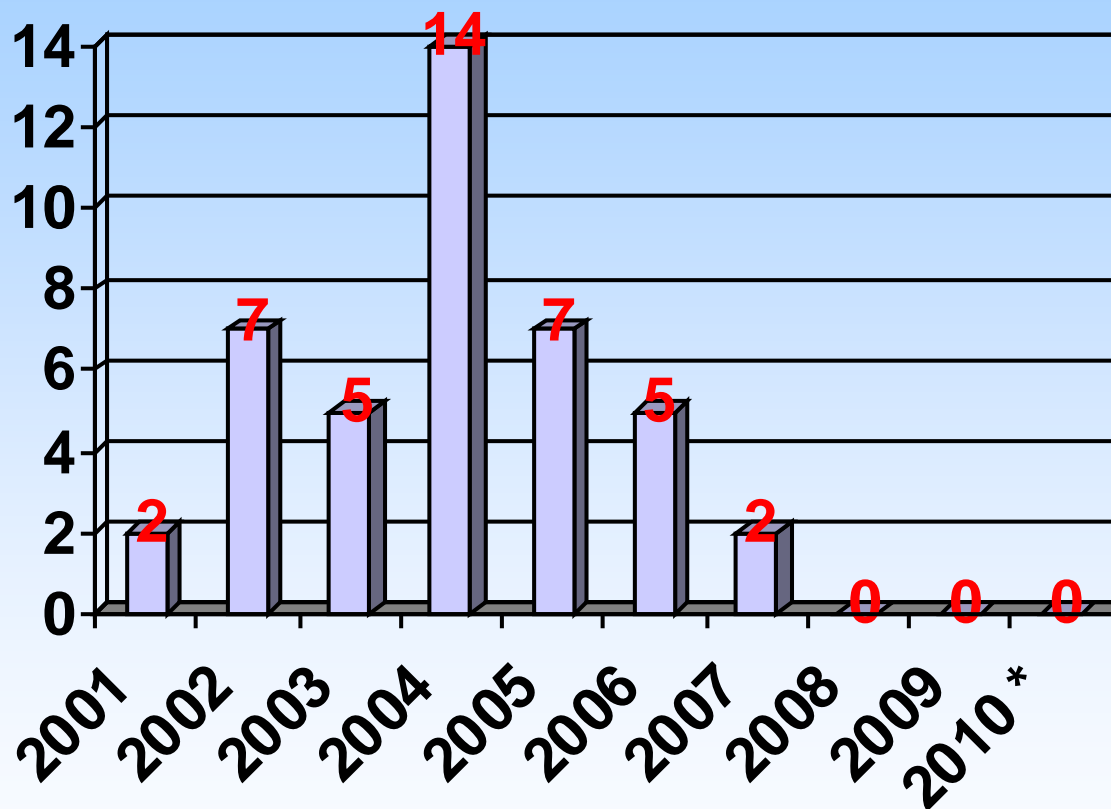
Staff Costs:

FTE reduced nearly 15% over past two years as result of process improvement

- **Despite increasing compliance burden**

Mayo A-133 Audit Trend

(Research Specific)



 # of A-133 Findings



Questions/Discussion