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

Susan Uhlenkamp, Chair, Research Finance, Mayo Clinic
Marco Wageman, Director, Research Finance, Mayo Clinic
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

- NIH: 72%
- Commercial: 14%
- Other Gov: 10%
- FDN / Associations: 4%
# Sources of Research Funding*

## Extramural

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

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>60%</td>
<td>$343M</td>
</tr>
<tr>
<td>Other Government Agencies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dept of Defense</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industry/Commercial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Profit Agencies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Intramural

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

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income from Operations</td>
<td>40%</td>
<td>$211M</td>
</tr>
<tr>
<td>Development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endowment Return</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operations Fundraising</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royalty Sharing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Extramural sources account for 60% of the funding, totaling $343M. Intramural sources account for 40% of the funding, totaling $211M.*
### Top Ten Sources of NIH Funding by Institute / Center

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

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

1. Leadership commitment
2. Policies & procedures
3. Compliance training
4. Resources
5. Tools
6. Communication

CP1282280-1
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

- Management Commitment
  - Start
- Continuous Improvement
- Customer Service & Satisfaction
- Measurement & Analysis
- Competence, Awareness, & Training
- Documentation System
- Culture
- QMS Administration

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

Continuous Improvement
Management Commitment
START
Culture
Customer Service & Satisfaction
QMS Administration
Measurement & Analysis
Competence, Awareness, & Training
Documentation System
Management Commitment
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.
Culture
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
Documentation System
Measurement & Analysis
### Financial Status Report Summary

<table>
<thead>
<tr>
<th></th>
<th>Completed on Time in Current Period</th>
<th>Complete From Prior Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># Due</td>
<td># Complete</td>
</tr>
<tr>
<td>January</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>February</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>March</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>April</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>May</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>June</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>July</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>August</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>September</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>October</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>November</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>December</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td><strong>Total YTD 2010</strong></td>
<td>208</td>
<td>206</td>
</tr>
<tr>
<td><strong>Total 2009</strong></td>
<td>162</td>
<td>161</td>
</tr>
</tbody>
</table>
## Federal Grant Review Summary

<table>
<thead>
<tr>
<th></th>
<th>6-Month Reviews</th>
<th>9-Month Reviews</th>
<th>12-Month Reviews</th>
<th>14-Month Reviews</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Reviews Due</td>
<td>% Completed On Time</td>
<td>Total Reviews Due</td>
<td>% Completed On Time</td>
</tr>
<tr>
<td></td>
<td>Associate</td>
<td>Specialist</td>
<td>Associate</td>
<td>Specialist</td>
</tr>
<tr>
<td>Jan</td>
<td>184</td>
<td>99%</td>
<td>100%</td>
<td>65</td>
</tr>
<tr>
<td>Feb</td>
<td>82</td>
<td>100%</td>
<td>98%</td>
<td>0</td>
</tr>
<tr>
<td>Mar</td>
<td>135</td>
<td>95%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>Apr</td>
<td>1</td>
<td>100%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>May</td>
<td>0</td>
<td>100%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>June</td>
<td>17</td>
<td>100%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>July</td>
<td>34</td>
<td>100%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>Aug</td>
<td>35</td>
<td>100%</td>
<td>97%</td>
<td>0</td>
</tr>
<tr>
<td>Sept</td>
<td>70</td>
<td>100%</td>
<td>96%</td>
<td>0</td>
</tr>
<tr>
<td>Oct</td>
<td>53</td>
<td>100%</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>Nov</td>
<td>43</td>
<td>100%</td>
<td>86%</td>
<td>0</td>
</tr>
<tr>
<td>Dec</td>
<td>59</td>
<td>100%</td>
<td>0</td>
<td>100%</td>
</tr>
</tbody>
</table>
Performance Reviews Past Due
Goal: 0

Reviews Past Due
Customer Service & Satisfaction
Continuous Improvement
Does it Work?
Indicators of Success

Quality = Service and Outcomes

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

- 2001: 2
- 2002: 7
- 2003: 5
- 2004: 7
- 2005: 14
- 2006: 5
- 2007: 2
- 2008: 0
- 2009: 0
- 2010*: 0

*Note: Data for 2010 is not available.
Questions/Discussion