UNIVERSITY RESEARCH STRUCTURE
AND RESOURCES

Brown Bag Seminar Series

Denise McCartney
Associate Vice Chancellor for Research Administration

November 19, 2013
Academic Medical Centers

MISSION

- Clinical Practice
- Teaching
- Research
- Community Service

These missions are increasingly overlapping
Patient Care

Patient Care in an AHC provides:

- Teaching Models for Students
- Clinical Experience for Residents, RNs, Therapists and Others
- Research Opportunities
  - Local
  - National
  - International
  - Or collaborative and a mix of all
- Translational & Outcome Research
- Community Service
Teaching

Teaching is a Core Mission:

- Expansion of Knowledge
- Share Knowledge with Community
- Continuity of Knowledge
Research

Research overlaps with Patient Care and Teaching

- Train students, postdocs, graduate students, physicians, nurses, physical therapists and more
- Cutting Edge Patient Care
- Expand Knowledge via Research
- Share Knowledge with Community
- Community Service
## Research Funding by Sponsor Type – FY 13

Research Award Dollars ($ 000’s)

<table>
<thead>
<tr>
<th></th>
<th>With ARRA</th>
<th>w/o ARRA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FY09</td>
<td>FY10</td>
</tr>
<tr>
<td>Federal</td>
<td>437,435</td>
<td>535,043</td>
</tr>
<tr>
<td>State/Local/Int'l</td>
<td>18,662</td>
<td>24,805</td>
</tr>
<tr>
<td>Private</td>
<td>111,285</td>
<td>146,439</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>567,383</td>
<td>706,288</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>w/o ARRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>437,435</td>
</tr>
<tr>
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</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>567,383</td>
</tr>
</tbody>
</table>

### ARRA

- NIH: 63%
- NSF: 3%
- Other Fed: 7%
- Other Gov't: 5%
- Industry: 3%
- Non-Profit: 19%

ARRA: $701
<table>
<thead>
<tr>
<th></th>
<th>FY08</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arts &amp; Sciences</td>
<td>41,278</td>
<td>42,925</td>
<td>46,993</td>
<td>33,482</td>
<td>40,578</td>
<td>43,033</td>
</tr>
<tr>
<td>Engineering</td>
<td>23,480</td>
<td>24,010</td>
<td>28,624</td>
<td>23,284</td>
<td>23,200</td>
<td>24,686</td>
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<tr>
<td>Medicine</td>
<td>471,753</td>
<td>483,915</td>
<td>596,130</td>
<td>545,158</td>
<td>436,444</td>
<td>464,507</td>
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<tr>
<td>Social Work</td>
<td>8,370</td>
<td>14,735</td>
<td>19,556</td>
<td>14,099</td>
<td>17,750</td>
<td>16,502</td>
</tr>
<tr>
<td>Other</td>
<td>3,470</td>
<td>1,798</td>
<td>14,986</td>
<td>1,623</td>
<td>1,623</td>
<td>1,975</td>
</tr>
<tr>
<td>Total</td>
<td>$548,351</td>
<td>$567,383</td>
<td>$706,288</td>
<td>$617,646</td>
<td>$620,408</td>
<td>$550,703</td>
</tr>
</tbody>
</table>

* Does not include industry sponsored clinical trials,
## WUSTL External Sponsored Research
### FY09 – FY13 including ARRA
#### Award Dollars (000,000’s)

<table>
<thead>
<tr>
<th></th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>Change FY12-13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Federal</strong></td>
<td>$437</td>
<td>$535</td>
<td>$468</td>
<td>$452</td>
<td>$404</td>
<td>-11%</td>
</tr>
<tr>
<td><strong>State/Local/Int'l</strong></td>
<td>19</td>
<td>25</td>
<td>26</td>
<td>24</td>
<td>25</td>
<td>--</td>
</tr>
<tr>
<td><strong>Private Industry</strong></td>
<td>19</td>
<td>25</td>
<td>19</td>
<td>16</td>
<td>15</td>
<td>--</td>
</tr>
<tr>
<td><strong>Private Nonprofit</strong></td>
<td>93</td>
<td>121</td>
<td>105</td>
<td>128</td>
<td>107</td>
<td>-16%</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>567</td>
<td>706</td>
<td>618</td>
<td>620</td>
<td>551</td>
<td>-11%</td>
</tr>
<tr>
<td><strong>Industry-Sponsored</strong></td>
<td>27</td>
<td>27</td>
<td>27</td>
<td>28</td>
<td>36</td>
<td>+29%</td>
</tr>
<tr>
<td><strong>Clinical Research</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$594</td>
<td>$733</td>
<td>$645</td>
<td>$648</td>
<td>$587</td>
<td>-9%</td>
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</table>
# Clinical Research FY11

<table>
<thead>
<tr>
<th>Department</th>
<th>FY 2011 Number</th>
<th>FY 2011 Dollars</th>
<th>FY 2010 Number</th>
<th>FY 2010 Dollars</th>
<th>FY 2009 Number</th>
<th>FY 2009 Dollars</th>
<th>% Inc / (Dec) FY 09 - FY 11 Number</th>
<th>% Inc / (Dec) FY 09 - FY 11 Dollars</th>
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</thead>
<tbody>
<tr>
<td>Internal Medicine</td>
<td>711</td>
<td>$13,454,716</td>
<td>794</td>
<td>$14,942,065</td>
<td>724</td>
<td>$13,420,533</td>
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<tr>
<td>Neurology</td>
<td>151</td>
<td>2,020,335</td>
<td>144</td>
<td>1,917,933</td>
<td>124</td>
<td>1,989,327</td>
<td>22%</td>
<td>2%</td>
</tr>
<tr>
<td>Surgery</td>
<td>130</td>
<td>2,278,585</td>
<td>117</td>
<td>1,673,053</td>
<td>136</td>
<td>1,749,474</td>
<td>-4%</td>
<td>30%</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>99</td>
<td>1,426,494</td>
<td>93</td>
<td>1,329,103</td>
<td>86</td>
<td>1,031,996</td>
<td>15%</td>
<td>36%</td>
</tr>
<tr>
<td>Radiology</td>
<td>58</td>
<td>756,670</td>
<td>63</td>
<td>1,364,864</td>
<td>62</td>
<td>2,182,770</td>
<td>-6%</td>
<td>-65%</td>
</tr>
<tr>
<td>Obstetrics &amp; Gynecology</td>
<td>32</td>
<td>1,530,071</td>
<td>29</td>
<td>713,199</td>
<td>28</td>
<td>479,948</td>
<td>14%</td>
<td>219%</td>
</tr>
<tr>
<td>Pathology &amp; Immunology</td>
<td>28</td>
<td>182,676</td>
<td>33</td>
<td>763,462</td>
<td>44</td>
<td>1,158,274</td>
<td>-36%</td>
<td>-84%</td>
</tr>
<tr>
<td>Orthopedic Surgery</td>
<td>24</td>
<td>690,760</td>
<td>19</td>
<td>426,628</td>
<td>24</td>
<td>1,116,948</td>
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<tr>
<td>Psychiatry</td>
<td>22</td>
<td>1,767,354</td>
<td>22</td>
<td>1,598,850</td>
<td>28</td>
<td>2,066,684</td>
<td>-21%</td>
<td>-14%</td>
</tr>
<tr>
<td>Siteman Cancer Center</td>
<td>20</td>
<td>647,230</td>
<td>17</td>
<td>562,899</td>
<td>13</td>
<td>503,602</td>
<td>54%</td>
<td>26%</td>
</tr>
<tr>
<td>Ophthalmology &amp; Visual Sciences</td>
<td>16</td>
<td>518,272</td>
<td>15</td>
<td>294,342</td>
<td>13</td>
<td>382,366</td>
<td>23%</td>
<td>36%</td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>13</td>
<td>458,401</td>
<td>14</td>
<td>257,622</td>
<td>17</td>
<td>162,430</td>
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<td>182%</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>10</td>
<td>683,023</td>
<td>12</td>
<td>747,059</td>
<td>7</td>
<td>847,618</td>
<td>43%</td>
<td>-19%</td>
</tr>
<tr>
<td>Neurological Surgery</td>
<td>8</td>
<td>111,495</td>
<td>6</td>
<td>60,574</td>
<td>16</td>
<td>60,110</td>
<td>-50%</td>
<td>85%</td>
</tr>
<tr>
<td>Otolaryngology</td>
<td>7</td>
<td>55,108</td>
<td>9</td>
<td>7,570</td>
<td>10</td>
<td>53,158</td>
<td>-30%</td>
<td>4%</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>5</td>
<td>62,955</td>
<td>3</td>
<td>39,680</td>
<td>7</td>
<td>33,148</td>
<td>-29%</td>
<td>90%</td>
</tr>
<tr>
<td>Developmental Biology</td>
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<td>-</td>
<td>1</td>
<td>1,500</td>
<td>3</td>
<td>28,500</td>
<td>-33%</td>
<td>-100%</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>1</td>
<td>35,241</td>
<td>1</td>
<td>14,684</td>
<td>0</td>
<td>-</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>1</td>
<td>-</td>
<td>2</td>
<td>16,316</td>
<td>2</td>
<td>10,000</td>
<td>-50%</td>
<td>-100%</td>
</tr>
<tr>
<td>Biochemistry &amp; Molecular Biophysics</td>
<td>1</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-50%</td>
<td>0%</td>
</tr>
<tr>
<td>Molecular Microbiology</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Health Behavior Research</td>
<td>1</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Health Administration</td>
<td>0</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Biostatistics</td>
<td>0</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>-100%</td>
<td>0%</td>
</tr>
<tr>
<td>Molecular Biology &amp; Pharmacology</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Div of Comparative Medicine</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,341</strong></td>
<td><strong>$26,679,386</strong></td>
<td><strong>1,400</strong></td>
<td><strong>$26,731,393</strong></td>
<td><strong>1,348</strong></td>
<td><strong>$27,277,086</strong></td>
<td><strong>-1%</strong></td>
<td><strong>-2%</strong></td>
</tr>
</tbody>
</table>

Table 1

Industry Sponsored Clinical Trials - School of Medicine – FY09-FY11
Clinical Research at WUSM

- All clinical departments
- Federal, Foundation and Industry Sponsors
- Centers
  - Siteman Cancer Center
  - Institute for Clinical and Translational Sciences
  - Alzheimer’s Center
  - And many more
WHAT A PLACE TO WORK

Excited, Committed Staff and Faculty

Energy of Discovery

Service Opportunities

Better World
Research Is A Privilege and Responsibility

We Should Conduc Research:

- Ethically and Responsibly
- Objectively
- With Integrity
- Protect Human and Animal Subjects
- Publish Results
- Translate Outcomes for Public Good
- Ensure the Proper Stewardship of Funds
But Things Go Wrong!

- Death of Human Subjects
- Improper Use of Sponsored Funds
- Misconduct of Research
- Violation of local, state and federal laws
- Improper Billing for Clinical Trials
- Betray the trust of the public, the students and the patients served
- Conflicts of Interest
University Oversight Mechanisms

- Develop Policies, Procedures, Standards
- Clarify Roles and Responsibilities
- Provide Education and Communication
- Implement Effective Organizational Structures
- Monitor
- Audit
- Receive and respond to allegations of wrongdoing
- High Level University Oversight
Develop Policies, Procedures, Standards

- Code of Conduct
  - [http://codeofconduct.wustl.edu](http://codeofconduct.wustl.edu)

- Multiple Research websites
  - [http://research.wustl.edu](http://research.wustl.edu)

- Environmental Health & Safety
  - [http://ehs.wustl.edu](http://ehs.wustl.edu)

- Clinical Research
  - [http://research.wustl.edu/ComplianceAreas/clinical/Pages/home.aspx](http://research.wustl.edu/ComplianceAreas/clinical/Pages/home.aspx)
Develop Policies, Procedures, Standards

- Reflects Regulations or Laws
  - Human Subjects Protections, EH&S,
- Reflects Commitment to Financial Stewardship – Role of SPA
- Reflects University Values
  - Conflict of Interest
- Reflects University Mission
  - hEsc
The goal of the Roles and Responsibilities document is to provide comprehensive descriptions of the duties of key individuals and organizational units that design, conduct, report, and/or support research activities at Washington University.

Roles & Responsibilities:  http://roles.wustl.edu/
Clarify Roles & Responsibilities

**University:**

- Official grantee
- Accountable to sponsors, donors, patients, students, and faculty
- Partners with Faculty Investigators and Research Team Members
- Partners with Industry and Community Services
- Responsible for the provision of certain resources
- Report results of research

Roles & Responsibilities: [http://roles.wustl.edu/](http://roles.wustl.edu/)
Clarify Roles & Responsibilities

**Principal Investigators:**
- Design Research Projects
- Conduct Research Ethically and Objectively
- Maintain the integrity of the data
- Maintain the trust of the patients and community they serve
- Protect the environment and employees

Roles & Responsibilities: [http://roles.wustl.edu/](http://roles.wustl.edu/)
Clinical Research Coordinators:

- Supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.

- Works with the PI, department, sponsor, and institution to support and provide guidance on the administration of the compliance, financial, personnel and other related aspects of the clinical study.
Provide Education and Communication

- Education is a major focus at WU
- Provided by a number of different entities
  - HRPO
  - Research Education & Information
    [http://research.wustl.edu/events/Pages/UpcomingEvents.aspx](http://research.wustl.edu/events/Pages/UpcomingEvents.aspx)
  - ResearchNews
    [http://researchnews.wustl.edu/](http://researchnews.wustl.edu/)
  - Center for Clinical Studies
- On-line training
  - Humans Subjects, Effort Reporting, etc.
- Responsible Conduct of Research (RCR)
  - [http://research.wustl.edu/resources/PERCSS/Pages/PERCSS.aspx](http://research.wustl.edu/resources/PERCSS/Pages/PERCSS.aspx)
- Clinical Research Progress
  - ICTS
  - WU Ucollege
    - Certificate in Clinical Research Management
    - Master of Clinical Research Management
Key Tools

- Research at WU -- [http://research.wustl.edu/](http://research.wustl.edu/)
- Research Gateway -- [https://research.wustl.edu/Pages/ResearchGateway.aspx](https://research.wustl.edu/Pages/ResearchGateway.aspx)
- Compliance Profile -- [http://complianceprofile.wustl.edu/](http://complianceprofile.wustl.edu/)
Provide Effective Organizational Structures

- Research Support Offices/Committees
- Research Compliance Offices
- University Offices
Monitoring

- Internal
  - HRPO Programs
  - Human Subjects Research Quality Assurance/Quality Improvement Committee
  - Siteman QASM

- External
  - Study Monitors
  - Sponsors
  - FDA
Auditing

- Internal
  - Research Compliance Reviews by the University Compliance Office
  - Internal Audit

- External
  - FDA
  - OHRP
  - NIH
  - Other Sponsoring Agencies
    - BJHF
  - OIG
  - DOJ
  - CAO
  - NSF
  - DEA
  - AND MANY MORE . . .!

WU is a nice place to audit!
Audit Guidelines

http://universitycompliance.wustl.edu/
Receive and Respond to Allegations

- University Hot Line
  - (314) 362-4998
  - http://universitycompliance.wustl.edu/codeofconduct/Pages/Onlinereportingform.aspx

- Vice Chancellor for Research
  - (314) 362-7010

- Environmental Health and Safety
  - (314) 362-6816
Receive and Respond to Allegations

- Investigations (Internal or External)
- Response to Audits
- Education
- Sanctions
The True Picture

Washington University

Schools/Departments

PI

Department

Research Support

Research Administration Offices

- Review and Approve Protocols
- Pre-Award Certification
- Award Negotiation
- Review Approvals and Prior Approvals
- Provide Compliance Education
- Monitor Compliance
- Set Policies
- Provide tools
- Communicate Expectations

Active Participation...

Annual Disclosures

Financial Management

Reviewing Reports

Human Subjects Ed

Animal Education, EH&S

Internal Audit

Radiation Safety Procedures

Human Subjects Procedures

Human Subjects Policies & Education

Environmental Health & Safety Policies & Education

RCR Policies & Procedures

RCR Procedures

Sponsor Institutions

Congress

State, Local Government

Oversight Agencies

Other Academic Institutions
QUESTIONS?