



OREGON  
HEALTH & SCIENCE  
UNIVERSITY

# OHSU Board of Directors Meeting

March 20, 2012  
SON – 358/364  
1:00 p.m. – 3:00 p.m.

# OREGON HEALTH & SCIENCE UNIVERSITY BOARD OF DIRECTORS MEETING

Tuesday, March 20, 2012

1:00 – 3:00 p.m.

School of Nursing, Rooms 358 & 364

1:00 p.m.	Call to Order/ Chairman's Comments	Charles Wilhoite
	President's Comments	Joe Robertson
	Approval of Minutes <b>(Action)</b>	Charles Wilhoite
1:15 p.m.	Financial Report	Lawrence Furnstahl
1:35 p.m.	Annual Report of Integrity Program	Ronald Marcum
1:55 p.m.	Annual OHSU Healthcare Quality Report	Chuck Kilo
2:15 p.m.	Facilities Master Plan	Brian Newman
2:35 p.m.	Research Roadmap	Mary Stenzel-Poore Jeanette Mlandenovic
3:00 p.m.	Other Business; Adjournment	Charles Wilhoite

**NEXT MEETING:**

**WEDNESDAY, JUNE 27, 2012**

**1:00 – 3:00 P.M.**

**OHSU SCHOOL OF NURSING**



**Oregon Health & Science University  
Board of Directors Meeting  
December 1, 2011**

Board Members in Attendance: Charles Wilhoite, Román Hernández, Rachel Pilliod, Maria Pope, Joe Robertson, Jay Waldron, Meredith Wilson, David Yaden, Jon Yunker,

Staff Presenters: Lawrence Furnstahl, Fred Coccodrilli, Amy Wayson, Mark Richardson

**Chair's Comments**

Mr. Wilhoite welcomed everyone to the Board meeting, noting that the pace of work at OHSU does not slow down notwithstanding the holidays. Mr. Wilhoite outlined the agenda and invited Joe Robertson to present the President's report.

**President's Comments**

Dr. Robertson began his remarks by noting the accomplishments of academic leaders who are stepping down - School of Dentistry Dean Jack Clinton and School of Nursing Dean Michael Bleich. Dean Clinton's dream has been to replace the current dental school with its current \$25 million of deferred maintenance. Many of the donors for the new Skourtes Tower were generous in their giving because of their personal relationships with Dean Clinton. In addition to his fundraising efforts, Dr. Clinton accomplishments include the establishment of an entrepreneurial business model for the school that will ensure long term financial viability, and the reinstatement of the pediatric dentistry residency program. Dr. Robertson reported that Gary Chiodo will transition from his role as Chief Integrity Officer to serve as the Interim Dean at the School of Dentistry while a national search is conducted. Dr. Chiodo graduated from the OHSU School of Dentistry and practiced at the Russell Street Dental Clinic for 21 years prior to his various roles at OHSU including Professor of Community Dentistry and Associate Director of the Center for Ethics and Healthcare.

Dr. Robertson noted that Dean Michael Bleich has stepped down from his position as Dean of the School of Nursing and will continue as the Dr. Carol Lindeman Distinguished Professor of Nursing. Dean Bleich's contributions included strengthening the leadership on each campus, streamlining and standardizing support staff roles, building key organizational processes, and developing a strategic plan that dovetailed with OHSU's strategic plan. Provost Jenny Mladenovic will name an Interim Dean of the School of Nursing by January 30. A search firm will conduct a national search for Dean Bleich's replacement.

Dr. Robertson recounted that construction of the Collaborative Life Science (CLS) Building is rapidly progressing at the South Waterfront. He noted that philanthropy and partnership has enabled the vision for the CLS Building to become reality. The CLS Building will be approximately 675,000 square feet, and involve building costs of about \$295 million. The goal is for the CLS Building to be partially open for classes in the fall of 2013, with completion in the spring of 2014. The CLS Building is designed to achieve LEED (Leadership in Energy and Environmental Design) platinum status. This status was achieved by the Center for Health & Healing, a building that subsequently received double LEED status, recognizing achievement in building operation as well as construction.

Dr. Robertson commented that Southwest Moody Street has reopened and has largely been rebuilt, and the Gibb Street pedestrian bridge is progressing with completion expected in three to four months. The tram bioswale will be covered to add capacity for bike parking for the estimated 1200 employees and students who commute by bike in the summer.

OHSU's Tech Transfer team entered into a record number of agreements for industry-sponsored research projects during FY 11. These 118 agreements involve over \$12 million in awards for the scientists, the highest amount recorded by the University's research community to date. It was also a record year for material transfer agreements (466), non-disclosure agreements (117), invention disclosures (128), and agreements for products developed via OHSU-created or OHSU-owned intellectual property (49).

Dr. Robertson reported that Dr. Joe Gray, a recent "dream team" recruit to the Knight Cancer Institute, was elected to the Institute of Medicine, one of the highest honors a scientist can achieve.

Regarding healthcare reform, Dr. Robertson noted that while federal health care reform is focused on 2014, changes at a state level will have effect as early as next July. Oregon faces a Medicaid funding deficit of over \$600 million, taking into account federal matching funds. The Legislature will be defining how a Medicaid-funded Coordinated Care Organizations (CCO's) will operate. The Legislature's effort will be informed by a report from the Oregon Health Policy Board on which Dr. Robertson sits, and a number of working committees in which many OHSU employees participate. Efforts are ongoing to drive collaboration among health systems to design a system that serves the Medicaid patient population in a more cost effective manner.

Mr. Wilhoite acknowledged Dean Bleich and Dean Clinton for their valuable contributions to OHSU. He also recognized Dr. Gray's noteworthy accomplishments. Comments were added by other Board members about the number of world class scientists who choose to work at OHSU, including mention of Dr. Kent Thornburg, who is doing world leading research at OHSU on prenatal care and the effects of birth weight, and whose work has been written up in the *New Yorker* magazine.

### **Approval of Minutes**

Mr. Wilhoite asked for approval of the minutes of the October 6, 2011 and October 31, 2011 Board meetings, included in the Board Docket. David Yaden noted that the minutes from October 6 should be corrected to reflect that he was not in attendance at that meeting. Upon motion duly made and seconded, (i) the minutes for the October 6, 2011 meeting as amended to remove Mr. Yaden as an attendee, and (ii) the minutes for the October 31, 2011 meeting as submitted, were unanimously approved.

### **Financial Update**

Mr. Furnstahl referred the Board to the financial results through October, noting that the FY '12 budget calls for maintaining earnings of \$57 million to fund our capital projects. Continued downward pressure on government funding, along with an increase in pension costs of \$20 million for PERS represent significant challenges. Actual operating income for the first 4 months of the year was \$14.1 million against an expected \$16.6 million, a variance that is not unusual in the early months of the fiscal year. Revenue is \$20 million less than budgeted, but that reduction is offset by \$18 million less than budget in expenses for the period. This is primarily due to the pace of spending federal grants. In addition, although patient activity is up over last year, it is not as high as budgeted, with surgical volume down.

Referring to the income statement, Mr. Furnstahl noted the decline in spending of government grants and in patient activity. The declines are for the most part recouped by the reductions in expenses. Going forward, patient activity will be monitored closely, particularly in surgical areas. Mr. Furnstahl commented that the significant decline in operating income compared to last year is a product of the timing of the booking of restricted revenues. This disparity will be cleared by November of this year.

Referring to the balance sheet, Mr. Furnstahl pointed out that total net worth for the first four months is down \$15 million, a modest decrease on a \$1.9 billion base. The two offsetting factors producing this are the

positive operating income year to date of \$14 million, offset by the decrease in the stock market returns on endowments held at the Foundation. Cash and investments held directly by OHSU remain fairly level, as a result of the offsetting of depreciation by capital expenditures, operating income of \$14 million and the payment of most of the principal payments on debt in July. Mr. Furnstahl observed that generally, cash holdings tend to decrease in the first half of the year and increase during the second half of the year.

### **Debt Restructuring Update Resolution 2011-12-07**

At Mr. Wilhoite's invitation, Mr. Furnstahl described the proposed debt restructuring. Mr. Furnstahl reported that the Finance & Audit Committee has worked with an internal OHSU team and external advisors to optimize the debt structure to achieve the lowest cost of capital. Referring to his summary included in the Board materials, Mr. Furnstahl explained that the proposed Resolution authorizes the restructuring of \$210 million of variable rate debt, of the \$730 million in total outstanding debt. The plan is to take advantage of currently favorable credit capacity and low interest rates. The Resolution contemplates no new debt at this time; however later in the year, \$85 million will be needed to complete the CLS Building. Mr. Furnstahl explained that currently, approximately 28% of OHSU's outstanding debt is variable rate debt, with the remainder fixed rate debt bearing interest on average at 5.4%. Variable rate debt includes \$130 million of auction rate notes and \$80 million of variable rate demand bonds, much of which has interest rate swaps associated with it.

Mr. Furnstahl explained that variable rate debt provides a lower cost of capital over time, but carries with it credit risk, liquidity risk, bank risk and tax policy risk. Managing these risks by planning on approximately 25% in variable rate debt and 75% in fixed rate debt, and holding 3 times as much in fixed income investments as variable investments, results in a natural hedge on our balance sheet. Risks can also be managed by using more than one credit provider, choosing strong banks as partners, staggering the maturity dates and maintaining a strong credit rating.

Mr. Furnstahl reported that in connection with the restructuring, OHSU pursued RFP processes resulting in nine responses from major banks and a response to the RFP for remarketing services from three minority business enterprise firms. As a result of those processes, we are proposing that \$130 million be provided by U.S. Bank and \$80 million by the Royal Bank of Canada. These firms' responses reflected best pricing, deepest credit capacity, and superior credit ratings. As a result of the MBE/WBE RFP process, we propose that Loop Capital Markets, a firm with an excellent track record and lower fees, remarket part of the bonds. Mr. Furnstahl commented that this choice reflects how diversity expands the pool of possible business partner and also yields good value.

Walking through a rough estimate of the savings resulting from the proposed variable rate restructuring, Mr. Furnstahl indicated that it could be as much as a point savings on \$200 million over a multi-year period. Mr. Furnstahl noted that an RFP will be issued to the same group of large banks for fixed rate debt to be issued later in the year for financing of the CLS Building. Mr. Furnstahl anticipates opportunities to refund or refinance existing debt at lower interest rates. Mr. Furnstahl indicated that Fred Coccodrilli would outline the Board resolution. Board member comments followed, thanking Mr. Furnstahl and his team for their efforts.

Mr. Coccodrilli outlined Resolution 2011-12-07, noting that a slightly revised (and redlined) version had been substituted for that in the Board packet docket. He called out the following key provisions of the Resolution:

- General authorization for management to pursue and complete the debt restructuring options,
- Authorization of the issuance of the new bonds,
- Authorization to management to address the existing interest rate swaps without entering into any new swaps,
- Authorization of the distribution of disclosure documents for the bonds,

- General authorization of any additional action by management as necessary to complete the transactions, and
- Confirmation that the State of Oregon is not responsible for any obligations incurred with the transaction.

Mr. Wilhoite commented that while \$730 million of total debt at OHSU might appear to be high, it represents only 30% of overall capital. The restructuring represents an important step in our objective of putting in place financing that is sustainable and allows for growth of the organization.

Mr. Wilhoite asked for approval of Resolution 2011-12-07, requesting authorization to restructure \$210 million of variable rate debt. Upon motion duly made and seconded, the Resolution was unanimously adopted.

### **Board Charters-- Resolution 2011-12-08**

Upon invitation, Jay Waldron reported the results from the annual Board survey. In general, the Board is pleased with the functioning of the Board, and particularly pleased with the Board Chair and the Finance & Audit Committee. The Board would like more presentations that highlight the “world” outside of OHSU that impacts OHSU as well as the internal “world” at OHSU, with details on healthcare education and research. The Board would like input from Executive Leadership Team that positions the Board to ask the right questions, and then the opportunity for discussion of those issues. Information regarding critical issues and requiring Board action should be distributed to Board members as early as possible. Finally, the Board wants information about the effectiveness and implementation of the recent consultant work, including the ensuing discussion within the Executive Leadership Team of that work.

On Mr. Waldon’s invitation, Ms. Wayson outlined Resolution 2011-12-08 amending the Board charters in primarily housekeeping ways. Ms. Wayson noted that the Governance Principles and Guidelines and current Bylaws of the institution were included in the Board materials for reference purposes only, although no changes are proposed for these documents.

Mr. Wilhoite asked for approval of Resolution 2011-12-08. Upon motion duly made and seconded, the Resolution was unanimously adopted.

### **Committee Appointment Resolution 2011-12-09**

Mr. Waldron outlined Resolution 2011-12-09 reflecting the proposed composition of the Board committees. Wilhoite asked for approval of Resolution 2011-12-09. Brief discussion followed clarifying the length of tenure of Gary Chiodo on the Integrity Program Oversight Council. Upon motion duly made and seconded, the Resolution was unanimously adopted.

Mr. Wilhoite commented that the Board is well-informed and wants to be even better informed, recognizing that it must maintain an oversight not an operations role. Mr. Yaden clarified that he does not want more information, but rather information that focuses the Board on the significant issues requiring Board attention.

### **Bob and Charlene Moore Institute for Nutrition and Wellness Update**

On invitation, Dr. Mark Richardson described the recent \$25 million pledge to create the Bob and Charlene Moore Institute for Nutrition and Wellness. He recounted that a fourteen member committee of scientists, finance experts, and leaders from the School of Medicine was charged with determining how to make the biggest impact in this area in nine months, and to prioritize actions that will be visible to the donor and the community. The committee will also identify potential leadership and develop a job description for a leader of

the Institute, and look at foundational principles that will form the core of the Institute. The committee determined that the cornerstone of the Institute will focus on the developmental origins of health and disease, including the vital relationships between maternal-prenatal diet, fetal health, and adult onset disease. This will build on the internationally recognized strengths of OHSU. Foundational principles include: education through professional training and community outreach, research through clinical, basic, and translational science, clinical care through development of new preventative measures and treatments, and public policy advocacy to promote community nutrition.

An interim director will be appointed as the committee performs a national search for a director of the Institute, ideally a search that will be completed in six months. An inter-professional healthcare curriculum on nutrition will be developed and policies related to food labeling and the use of fructose in food products will be evaluated. OSU was identified as a potential partner to work on food labeling to ensure that food is accurately labeled. Responding to a Board question about performance enhancing substances, Dr. Richardson explained that our Atlas and Athena Program, which is part of the sports medicine and educational programs, will collaborate with the Nutrition and Wellness Center.

Dr. Robertson reported that in an effort to lead by example, the Executive Leadership Team is participating in a new OHSU program called "Healthy Team, Healthy U", a program that teaches wellness and nutrition. Involvement in the program is one of five ways that OHSU employees can receive reduced medical insurance rates by demonstrating the management and improvement of health. Mr. Wilhoite commented that nutrition is the cornerstone of health and recognized Bob and Charlene Moore for their generous donation that will make significant impacts in the future. Responding to a Board member, Dr. Richardson stated that there are a number of nutrition and wellness institutes across the country, but that OHSU will be only one of three that focuses on the interchange of diet, newborn prenatal health, and the influence on long-term health and disease.

### **Adjournment**

Mr. Wilhoite thanked Dr. Richardson. Hearing no further business, Mr. Wilhoite adjourned the meeting.

Respectfully submitted,

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Amy M. Wayson  
Board Secretary

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# FY12 February Financial Results

OHSU Board of Directors  
March 20, 2012

# FY12 February YTD Financial Results

- FY12 budget calls for maintaining earnings at \$57 million, against \$20 million of incremental pension cost and downward pressure on government funding.
- We anticipated \$27 million of operating income through February; activity and earnings across missions are usually lower in the first part of the fiscal year, due to the summer and holidays, as well as lags in drawing on gift support.
- Actual results are \$9 million above this pace, at \$36 million, with \$4 million less revenue more than offset by \$13 million less expense. The shortfall from budget reported during the early months of the year has been closed since December.
- Note that the budget included a \$14 million cut in Medicaid, which was reduced to only \$2 million through a higher Provider Tax on Oregon hospitals. This adds \$1 million per month to revenues compared to budget.
- February balance sheet and cash flow are not yet complete (pending final Foundation information), but will be presented at next week's meeting.

# Major Drivers of FY12 8 Month Performance

- Major drivers of results through February include four key productivity & process redesign initiatives:
  - Improved throughput with lower length of stay
  - Much lower service & supply expense
  - Greater than budgeted success in defensible pricing
  - And revenue cycle improvements.
- Patient activity is up 4.6% measured by CMI/OP adjusted admissions—while still -2% below budget, the gap is closing.
- End of ARRA/stimulus funding offset by 17% increase in non-ARRA grant awards.
- However, compensation is running \$9 million above budget, and should instead be flexing down with lower than budgeted activity and revenue.
- February YTD results also include \$4 million of net prior year gains, from reconciliation of retail pharmacy and student loan payments.

# 8-Month Earnings at \$36M (\$9M > Budget)

February YTD (millions)	FY11 Actual	FY12 Budget	FY12 Actual	Actual - Budget	Actual / Last Year
Net patient revenues	\$873.5	\$940.4	\$944.9	\$4.5	8%
Grants & contracts	238.6	242.7	236.8	(5.9)	-1%
Gifts	18.8	27.0	26.5	(0.5)	41%
Net tuition & fees	33.6	37.6	39.1	1.5	16%
State appropriations	23.9	23.6	23.6	0.0	-1%
Other revenue	67.6	58.0	53.9	(4.1)	-20%
Operating revenues	1,256.0	1,329.3	1,324.8	(4.5)	5%
Salaries & benefits	730.0	772.9	782.0	9.1	7%
Services & supplies	407.6	432.1	410.1	(22.0)	1%
Depreciation	70.7	72.3	73.3	1.0	4%
Interest	24.4	24.7	23.2	(1.5)	-5%
Operating expenses	1,232.7	1,302.0	1,288.6	(13.4)	5%
Operating income	\$23.3	\$27.3	\$36.2	\$8.9	55%

# FY12 February Results – Patient Activity

- Overall patient activity is up over last year, but yet not as much as targeted.
- First quarter shortfalls in surgical and other high-acuity activity (such as cancer, neuroscience and neonatology) impacted both case mix and payer mix, but this gap narrowed significantly during November – February.
- The activity shortfall is offset by higher realized payment rates from commercial activity and revenue cycle enhancements, and the temporary deferral of more severe Medicaid reductions made possible by a higher Provider Tax and federal match.
- Supplies & services are flexing downward with lower patient care volume and slower start to research spending, but so far compensation expense is not—the FY12 budget, unlike last year's, did not have as many unfilled positions to work with.
- The clinical enterprise continues to be highly focused on accelerating growth in surgical and other high-acuity programs, and all areas of the University are now focusing more closely on managing vacancies and hiring.

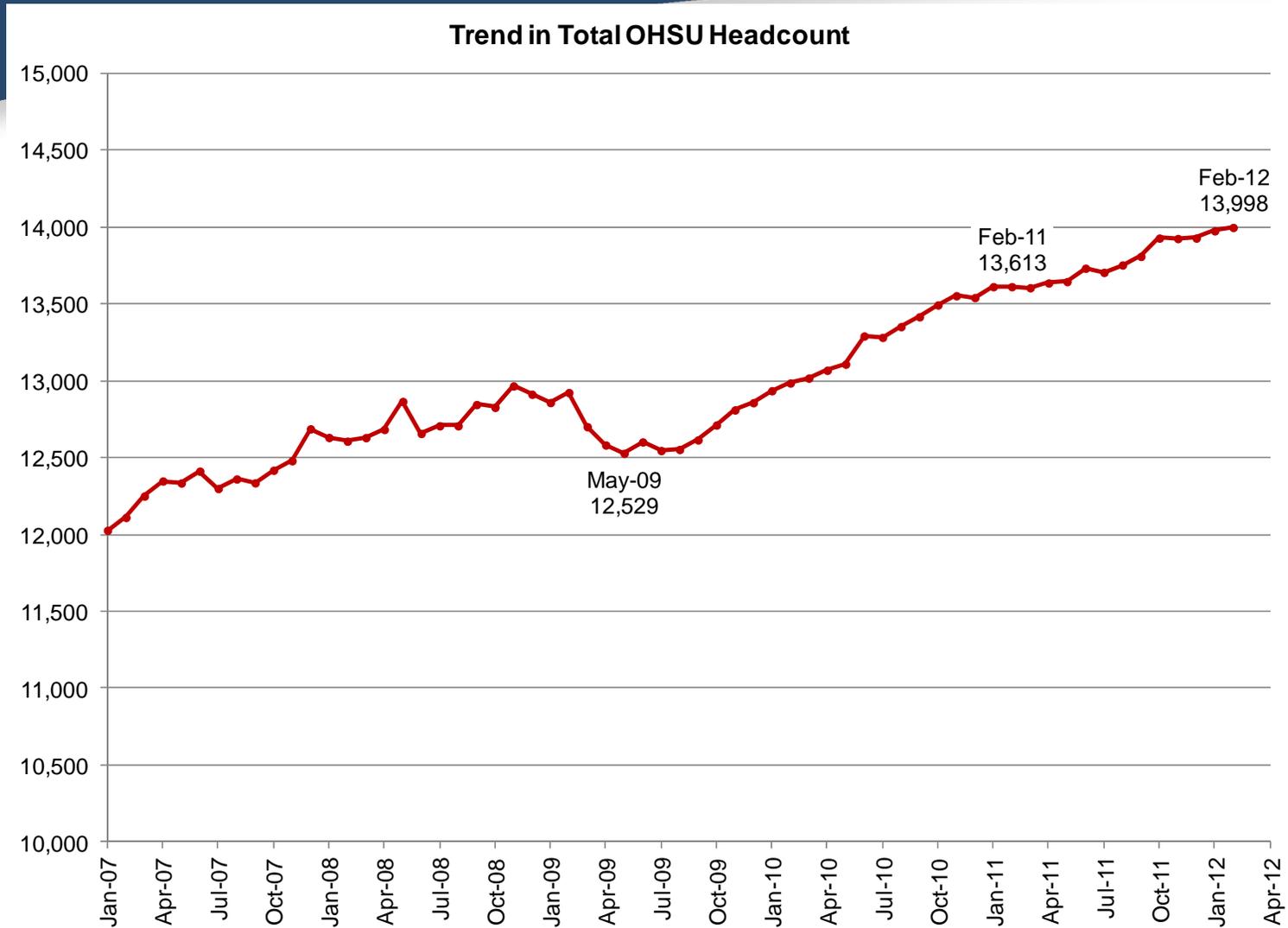
# Patient Activity Below Budget But Improving

February YTD	FY11 Actual	FY12 Budget	FY12 Actual	Actual / Budget	Actual / Last Year
Admissions	18,826	19,758	19,763	0.0%	5.0%
Average length of stay	5.7	5.6	5.3	-5.4%	-7.0%
Average daily census	430	434	420	-3.2%	-2.3%
Surgical cases	19,309	20,581	19,840	-3.6%	2.8%
Emergency visits	30,082	29,972	30,584	2.0%	1.7%
Ambulatory visits	451,731	484,319	479,646	-1.0%	6.2%
Casemix index	1.89	1.93	1.87	-3.1%	-1.1%
Outpatient share	41.7%	41.5%	42.1%	0.6%	0.4%
CMI/OP adj. admissions	61,042	65,239	63,858	-2.1%	4.6%

# New Grants Beginning to Fill Stimulus Gap

<b>Grant &amp; Contract Awards</b> December YTD (millions)	FY11 Actual	FY12 Actual	Actual / Last Year
Federal non-ARRA	\$111.2	\$131.7	18.4%
Federal ARRA/Stimulus	28.1	2.0	-92.9%
Non-federal	40.0	45.7	14.3%
Total grants & contracts	<u>\$179.3</u>	<u>\$179.4</u>	<u>0.1%</u>
<i>Number of awards</i>	763	868	13.8%

# Headcount Up 1,470 Since Financial Crisis



# Planning Considerations for FY13 Budget

- The State needs to cut \$239 million from its Medicaid budget in FY13 (the second year of the current biennium). In subsequent biennia, this cut is spread across two years.
- Due to the 37% Oregon / 63% federal funding of Medicaid, this would translate into a total cut of approximately \$646 million, on an annual base of \$3.2 billion.
- This impact should be moderated by new federal funds to support Medicaid transformation, plus federal match on sources outside of general funds. On net, we are planning for an FY13 payment reduction of about \$20 million for OHSU.
- To meet this challenge, while still generating a \$55 – 60 million operating margin to support capital investments, requires continued growth in patient activity with a stable commercial share.
- We would also need to maintain total staff at its current 14,000 headcount and manage total growth in salary + benefit cost per FTE.
- These goals require continued success in clinical strategy, process redesign and productivity initiatives.



## **OHSU INTEGRITY OFFICE ANNUAL REPORT**

to the

### **OHSU BOARD OF DIRECTORS**

Calendar Year 2011

*Presented March 20, 2012*

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# **Introduction to Calendar Year 2011 OHSU Integrity Office Annual Report**

In this Annual Report to the OHSU Board of Directors, we present information related to current national interest in all Integrity Program areas, how the OHSU Integrity Program has responded to those areas, and other integrity initiatives at OHSU. For easy reference, there is a **Glossary of Acronyms** beginning on page 14 of the report.

As the Board's aware, OHSU is currently recruiting a Chief Integrity Officer. Pending the hiring, Ronald G. Marcum, MD, serves as Interim Chief Corporate Integrity Officer; and Janet Billups, former OHSU Legal Counsel and Policy Advisor to the Vice President of Research, serves as Interim Chief Research Integrity Officer.

There are several areas that may include integrity or compliance issues but that are not included within the direct oversight of the Integrity Programs. Such areas include hospital Joint Commission standards, quality issues, contracting, employment rules, and many others. The direct oversight for those areas is handled in other departments; however, there is a high degree of coordination with the Chief Integrity Officer when appropriate. Because the Integrity Program at OHSU is now in its 12<sup>th</sup> year, this harmonization of oversight with several departments that may have integrity or compliance issues included within their broader responsibilities has matured and is relatively seamless.

## **I. National and Local Picture** *Integrity Issues of Current Focus*

### **A. National and Local Initiatives**

#### **1. Billing Audits: Recovery Audit Contractors, Medicare Area Contractors, Medicare Managed Care Audits**

The Centers for Medicare and Medicaid Services (CMS) recovery audit contractor (RAC) audit program was made permanent on January 1, 2009 and the program continues with increased audit activity across the U.S Medicare Administrative Contractor (MAC) and non-RAC Managed Care audits are also being conducted by contracted third parties without a limit the number audits for an institution in a given time period. The OHSU Hospital Clinical Integrity Program receives and processes all RAC, MAC and non-RAC Managed Care audit requests. This annual report to the Board will provide an update of RAC, MAC and non-RAC Managed Care Audits activities to date.

#### **2. Clinical Research Billing**

There is a high level of continued federal scrutiny of bills submitted for payment of services performed as part of a clinical research study. Institutions engaged in clinical research are devoting increased resources toward technology and staff to provide oversight and ensure compliance. It is imperative that these bills not include items or services: (1) paid for by clinical research sponsors or

grants; (2) intended to be free of charge as stated in the informed consent document; (3) performed for research purposes only; and (4) otherwise not covered under the Medicare Clinical Trial Policy.

### **3. New Conflict of Interest Regulations**

In August 2011, the National Institutes of Health (NIH) released new final rules for disclosure and management of financial conflicts of interest in research. The changes are in response to increasing national interest in apparent and real conflicts of interest and the impact on research and medicine. More detail is provided in Section V below.

### **4. Update of the Common Rule for Research**

An Advanced Notice of Proposed Rule Making (ANPRM) has been published by the Office for Human Research Protections (OHRP) and U.S. Food and Drug Administration (FDA) to update the “Common Rule”. The Common Rule which pertains to the protection of human subjects in the conduct of research, was last updated in 1981. The specifics of the ANPRM are discussed in Section III.

## **B. OHSU Initiatives**

### **1. The Knight Biolibrary**

The development of a coordinated repository strategy for the Knight Cancer Institute has been launched. Referred to as the Biolibrary, it is intended to be an organizational unit that will draw together existing specimen repositories and standardize future collection, management and distribution efforts, thereby enhancing the ability for researchers to conduct translational research. While the initial focus will be oncology repositories, the Biolibrary will have the flexibility to be expanded university-wide. With the current national attention on retaining and sharing specimens, there are many ethical, legal, and logistical frameworks to be defined before the Biolibrary can be launched. OHSU is carefully considering all aspects of the Biolibrary development so the new function will maintain OHSU’s reputation for quality patient care and innovative disease research.

Efforts to develop the Biolibrary are overseen by a Steering Committee that includes Executive Leadership and involves numerous work groups responsible for analyzing relevant ethical, legal, and logistical issues, and for developing recommendations on topics such as administrative oversight, informed consent, specimen handling, information technology, and community perspectives. The OHSU Research Integrity Office (ORIO) has representatives on three of these working groups (community engagement, informed consent and information technology).

- The community engagement team has conducted a series of focus groups with OHSU researchers and clinicians, as well as community representatives with special groups for minority and rural populations to gain both internal and external perspectives on biorepository activities.
- The informed consent group has conducted legal, ethical, and risk analyses of the types of samples that exist for future clinical and research experimentation, and what types of consent

or waiver of consent would and should be required. Items that need to be addressed include defining how consent will occur, return of research results to patients, inclusion of minors, and withdrawing consent. The processes for these activities will be informed by the focus group outcomes.

- The information technology group is considering how best to ensure security of protected health information that will be annotated against the specimens contained within the Bioblibrary.

## 2. Billing Audits

Since July 2008, OHSU has worked internally via a multi-department “RAC Task Force” to review the RAC findings and citations from other states and to review demonstration audits conducted from 2005 to 2007. In addition, our internal billing monitoring and auditing program looks for potential exposure in all areas. The monitoring includes hospital and clinics, professional, and clinical research billing activity. All elements of the OHSU clinical billing process are reviewed from front end process, encounter documentation, coding of service provided, submission of charges, and evaluation of payer responses through posting and reconciliation of payments received.

**a. RAC Audit Work.** CMS has contracted with the vendor HealthDataInsights (HDI) to audit all hospitals participating in the Medicare program in the State of Oregon. As of February 2, 2012, OHSU had received 54 automated denial notifications and 1265 complex inpatient requests from the RAC auditors. Automated denials of payments by the RAC auditors are generated by the auditor’s review of electronic billing data and do not require submission of documentation unless OHSU challenges the denial. Complex reviews require that the patient charts and all documentation to be submitted to the RAC.

The complex review requests have resulted in 147 denials (\$1.3M), 768 reviews that were upheld (\$23.9M), 89 that were underpaid (\$860K), and 255 (\$6.5M) that are pending review by HDI, our Medicare RAC audit company. There are 6 RAC requests (\$155K) that were rescinded by HDI. HDI has not provided a reason why these claims were rescinded. Of the 255 claims that are still pending review, 53 that are being audited for medical necessity as well as for correct DRG coding. The 147 denials were made up of 93 cases with coding errors and 54 cases related to medical necessity not supporting the billed inpatient status of the patients. The RAC process allows Noridian, the regional Medicare claims processor, to perform a secondary review of cases after the HDI review is completed. The purpose of this secondary review is to validate a sample of HDI reviews. When this happens, the “clock stops” in terms of times for appeals and other reviews. For example, the one case that was under review by Noridian was approximately 17 months old before it was resolved. We have appealed 14 (\$133K) denials and won eight (\$113K) and lost 2 (\$13K). The remaining 4 (\$6K) appeals are still awaiting a determination.

**b. MAC (Medicare Administrative Contractor) Audit Work.** In addition to the RAC audits of Medicare claims, Noridian is now performing complex reviews of services billed to determine if there are billing errors, fraud or abuse, or insufficient

documentation to support the services or level of services billed. Unlike the RAC audits, there are no limitations to the number of MAC audits that an institution can receive in a given period of time. OHSU has received 192 (\$101K) complex MAC audits during the period beginning July 2010. These audits are all related to immunosuppressant drugs supplied to transplant patients post-transplantation. These are all prepayment reviews. There are 77 (\$39K) denials and 115 (\$62K) reviews that were upheld, reflecting a denial rate of 40% (77 of 192). The average denial rate for all audited, per Noridian, is approximately 75%.

**c. Non-RAC Managed Care Audits.** As Medicare has been successful in finding dollars through their post payment audits such as RAC, Medicaid has initiated their own RAC audits (non-RAC audits). Non-RAC audits are conducted by a variety of third-party companies hired by the managed Medicare insurers. As of March, 2012, OHSU identified 404 (\$9.5M) non-RAC audits by various audit companies. About 45% of the cases are for United Health Care Medicare Managed Care patients and all are post-payment audits. There have been 56 (\$538K) denials, 116 (\$4.7M) claims upheld, and 223 cases still open (\$4.0M). We have appealed 23 (\$290K) cases and won 12 (\$221K) and lost 2 (\$4K). Nine appeal cases (\$65K) are still open. Of the 56 denials, 26 (\$278K) are related to medical necessity, 25 (\$236K) are related to coding and 5(\$24K) are related to an incorrect discharge disposition.

**d. Audit Tracking.** The Hospital Clinical Integrity Program implemented commercial software to assist in tracking claims that are reviewed via the RAC, MAC, and other auditing processes through all levels of appeal, if necessary. The software product tracks the status of each claim, generates reports related to the type of audit activity, and communicates to multiple departments that must assist in responding to the claims. We have developed a RAC/MAC/Non-RAC audit response team and an audit appeals team to coordinate all audit and appeals activities to ensure that our responses are within the mandated timelines.

If auditing or monitoring identifies a wrongfully billed service or submitted claim, an analysis of the process leading incorrect billing is conducted. If a process error is identified, it is corrected. Identified overcharges are corrected when identified and credit balances are refunded in a timely manner and in accordance with Medicare and other third-party payer requirements. As noted in the OHSU Clinical Compliance Plan, OHSU “is committed to preventing fraud and abuse in billing and are responsible to submit only charges that are truthful and accurate, that reflect medically necessary or appropriate services, and that are fully supported by health care record documentation. Attention is given to submitting as correct claim for payment the first time.

**e. Clinical Research Billing.** OHSU purchased a Clinical Research Management System in May of 2011 and is moving forward with development and implementation of a system to ensure compliance relating to billing for services performed as a part of a clinical trial. This system is designed to provide critical functionality for research patient tracking and billing and harmonizes with the Epic electronic medical record system.

Initial roll out is anticipated to be May 2012 with full implementation by the end of calendar year 2012.

### 3. Export Control Program

The U.S. Government has established rules and regulations regarding the export of commercial, research, and academic materials and information from the United States. These regulations may apply to shipping tangible items overseas, sharing certain information with foreign nationals at OHSU, or interacting with embargoed or sanctioned countries, organizations, and individuals. Academic research institutions are increasingly under Government scrutiny for compliance. OHSU has an obligation to comply with these rules and regulations, and as an employer of nearly 1400 foreign nationals, OHSU likely has more daily export transactions than any other company or institution in the region. To meet the compliance requirements, OHSU established the Office of Export Controls and recruited a subject matter expert. The OHSU compliance officer has over 15 years of experience working for the U.S. Department of Commerce. He was a Congressional Fellow advising U.S. Senators on trade policy, and consulted many exporting firms export compliance issues. Over the past year OHSU has implemented policy, training, and new procedures to ensure compliance with this set of complex U.S. Government regulations.

## II. Clinical Integrity

### A. National Picture

1. **OIG Work Plan:** The 2012 Work Plan, published by the Office of the Inspector General (OIG) in October 2011 provides insight into the clinical compliance risk areas that will receive particular governmental scrutiny. The 2012 Work Plan identifies risk areas that will be the focus of the OIG's investigations and inquiries. Many key areas of interest were also in previous Work Plans and include:
  - a. Accuracy of "Present on Admission" indicators submitted on Medicare claims;
  - b. Medicare Inpatient and Outpatient payments to acute care hospitals;
  - c. Acute-Care hospital inpatient transfers to inpatient hospice care;
  - d. Medicare payments for the drug Herceptin;
  - e. Medicare outpatient payments for drugs;
  - f. Laboratory utilization including the types of tests and the numbers of tests ordered;
  - g. Hospital same day readmissions;
  - h. Hospital reporting of adverse events; and
  - i. Hospital claims with high or excessive payments.
2. **Medicaid Audits:** In 2010, the Patient Protection and Affordable Care Act included a section on RAC-type audits for State Medicaid programs. In 2011, the State of Oregon contracted with a third-party company to perform these audits. The go-live date for these audits is in early 2012. Because each state will have its own Medicaid audit plan, OHSU will need to respond to multiple Medicaid RAC auditors as we have patients from surrounding states.

## **B. OHSU Initiatives**

### **1. Response to National Picture**

- a. Addressing the OIG Work Plan: Because the Annual OIG Work plans are a source of information for potential audits by the RAC auditors, the Hospital Clinical Integrity Program has included the Work plan's key areas of interest related to billing issues in its RAC preparation activities.
- b. Response to RAC, MAC, and Non-RAC Audits: We are utilizing the same RAC Task Force, software programs, and departmental organization to respond to all audits. OHSU is the largest Medicaid provider in the state and we work diligently with the Medicaid Program to make sure they receive all the documents requested in a timely manner.

### **2. Other Initiatives**

- a. Centralized Coding: In November 2008, the Hospital Clinical Integrity Program began assisting the Health Information Services (HIS) department in centralizing outpatient coding responsibilities for the Hospital. Assistance is still being provided anticipating completion by spring of 2012. This effort has centralized coding for the Emergency Department facility and professional fees, Family Medicine Resident Clinic, Infusion Clinics, and several other OHSU clinics. OHSU is hiring additional coding staff and additional departments are centralizing their facility services coding in HIS.
- b. Professional Fee Billing: The Professional Fee Billing component of the Integrity Office continues its program of conducting surveillance reviews of documentation and coding activity in School of Medicine departments. The purpose of the reviews is to ensure that documentation and coding of services billed is in full compliance with state and federal regulations and with billing rules for third party payers. The reviews highlight areas requiring continuing education at the department level.

## **III. Research Integrity**

### **A. National Picture**

#### **1. Human Subjects Research:**

- a. Advanced Notice of Proposed Rule Making (ANPRM): In an effort to update and improve the rules for the protection of human subjects, the Office for Human Research Protections (OHRP) and U.S. Food and Drug Administration (FDA) combined efforts to issue an ANPRM entitled Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators. The regulations pertaining to the protection of human subjects in the conduct of research, known as the "Common Rule," have not been

significantly changed since they were enacted in 1981. Specific proposals in the ANPRM include:

- Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.
- Using a single Institutional Review Board (IRB) for all domestic sites of multi-site studies.
- Updating the forms and processes used for informed consent.
- Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
- Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements and to make the collection of data more efficient.
- Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.
- Providing uniform guidance on federal regulations (i.e., harmonizing Common Rule, FDA, and Health Insurance Portability and Accountability Act (HIPAA) regulations)

- b. Oversight of research repositories (both tissue and data banks) continues to be an area of national interest and discussion and recent case law has elevated public awareness and interest in this issue. Variations in federal and state laws and the existence of genetic privacy acts in a few states have clouded this issue. In 2008, OHRP issued new guidance on research involving coded private information or biological specimens. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act proposes changes that will affect the consent and authorization process for protected health information that is banked for future research.
- c. In Vitro Diagnostics are subject to new guidelines from the FDA. In response to a scandal at Duke University, federal officials are stepping-up efforts to educate researchers about when to seek regulatory approval before using experimental genomic and proteomic microarray tests in clinical trials. Duke University drew attention because the in vitro diagnostic(s) (IVDs) under study in the Duke trial never received proper clearance from the FDA. The Duke IRB reportedly failed to require an Investigational Device Exemption (IDE) from the FDA for the IVD before starting the trials, even though they used the tests to determine treatment choices and stratify patients. Additionally, a lawsuit was recently filed on behalf of eight research participants alleging that the Duke clinical trials were fraudulent and occurred under false pretenses and that the participants were exposed to improper and unnecessary chemotherapy which delayed appropriate care.

## **2. Animal Subjects Research:**

The OHSU Central/Waterfront Campus and West Campus have remained fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALACi) following a site visit in the summer of 2010. OHSU's Central Campus animal care and use program has maintained continuous AAALACi accreditation since 1966. Additionally, recent inspections conducted by the United States Department of Agriculture identified no items of concern.

## **B. OHSU Initiatives**

### **1. Responses to National Picture**

- a. Human Subjects Research:
  - i. ANPRM: OHSU submitted comments to the proposed changes to the Common Rule during the open response session. OHSU representatives also participated in drafting comments for regional and national groups responding to the ANPRM.
  - ii. Research Repositories: The OHSU Research Repository policy was launched in June of 2010 in an effort to identify all repositories, and the compliance initiative was completed in August 2011. 275 repositories were identified and approved during this year-long project. OHSU is positioned well to access the latest and best thinking in this area, as Susan Bankowski, the OHSU IRB chair, is serving on the national Newborn Screening and Translational Research Network Bioethics and Regulatory Oversight Committee, which is focusing on issues related to stored tissue samples. The Knight Biolibrary efforts mentioned above reflect the institution's commitment to developing policy via a process that addresses all appropriate issues.
- b. In Vitro Diagnostics: The issue was considered by the IRB Chairs' Advisory Committee and remanded to a working group for consideration and policy development.
- c. Animal Subjects Research: Dr. Bill Dale started at OHSU in January of 2011 as the OHSU Research Integrity Officer for animal care and use on the Central/Waterfront Campus. Dr. Dale is a member of AAALACi and he has initiated review, development and implementation of policies and procedures that will help to assure maintenance of best practices and highest standards in the animal research programs.

## **IV. Institutional Biosafety**

### **A. National Picture**

#### **1. Select Agents and Other Infectious Agent Research:**

Research with Select Agents (infectious agents and toxins that have the potential to pose a severe threat to public health and safety) continues to be a hot topic of national discussion. In October of 2011, the U.S. Department of Health and Human Services released a proposed rule to revise the existing regulations pertaining to research with Select Agents. Existing regulations have been in place since 2005 and the final rule for

the current changes is expected in October of 2012. Changes in the proposed rule include:

- A new tiering system which places 11 of the 82 currently listed Select Agents as “Tier 1” pathogens that present the "greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence." (July 2010 Executive Order)
- Requirements for additional physical security, occupational health, and personnel reliability measures for laboratories that possess the Tier 1 agents.

## **B. OHSU Initiatives**

### **1. Select Agents at OHSU:**

OHSU maintains an active program of research involving Select Agents including some of the proposed Tier 1 agents OHSU is in compliance with current regulations which include significant biosafety, security, and incident response requirements for all Select Agent use. Although some of the additional requirements related to work with the Tier 1 agents were not specifically expressed in the proposed rule, it appears that OHSU would be in a good position to comply with the revised regulations and maintain its current research programs in this area.

## **V. Conflicts of Interest**

### **A. National Picture**

#### **1. NIH Requirements for Conflict of Interest in Research:**

In August 2011, the National Institutes of Health (NIH) released new final rules for disclosure and management of financial conflicts of interest in research. The new regulations come after much public attention to conflict of interest issues in science and medicine and include several substantial changes, including:

- Required disclosures, including:
  - all significant financial interests of a researcher related to his/her institutional responsibilities (previously, only those perceived as related to the investigator’s research need be disclosed);
  - researchers’ receipt of compensation or stock valued at greater than \$5000 (a decrease from the prior amount of \$10000); and
  - any reimbursed or sponsored travel provided to a researcher --excluding government or university sponsored travel – involving any amount of value. .
- 30 day timeline for disclosing new financial interests.
- In the event of non-compliance (such as a late disclosure), the requirement of the conduct of a retrospective review to determine if any Public Health Service (PHS)

funded research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

- Enhanced conflict of interest training requirements for investigators (to occur no less often than every four years).
- A significant increase in the amount of detail in required reporting to the NIH when a potential conflict of interest is found for PHS funded research.
- Requirements that institutions make certain information concerning identified conflicts of interest publicly accessible by either posting on a web site or by a written response to any requestor within five business days.

## **B. OHSU Initiatives**

### **1. Conflict of Interest in Research:**

The OHSU Research Integrity Office (ORIO) has begun work to develop optimal policies and procedures to implement the revised regulations. The ORIO is working with research representatives from many levels and areas of the institution to ensure that all perspectives are considered in determining how to configure processes and electronic systems to comply with the revised regulation. Compliance will require additional institutional resources.

## **VI. Information Privacy & Security**

### **A. National & State Picture**

#### **1. National Statistics:**

The most recent Office for Civil Rights posting as of mid-February 2012, shows the total number of privacy complaints received by the Office for Civil Rights (OCR) from April of 2003 through December of 2010 is 57,459. There have been 8524 complaints in 2010 with an 80% resolution rate. The top five complaints investigated by OCR continue to be impermissible uses and disclosures of protected health information (PHI), lack of safeguards for PHI, restricting access by patients to their own PHI, disclosing more than the minimum necessary PHI, and lack of the provision of the Notice of Privacy Practices to the patient.

#### **2. HITECH Act Reported Breaches:**

Since September 2009 and as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act, 358 breaches of unsecured PHI affecting 500 individuals or more have been reported to the Secretary of Health and Human Services. Of the 358 reports, 202 (56%) involved lost or stolen laptops or portable devices (including smartphones). New York City Health & Hospitals Corporation's North Bronx Healthcare Network had the largest reported breach of 2010 with 1.7 million patients affected. Two reports from 2010 and 2011 are from Oregon. Both involved

stolen computers and affected 4,328 and 1,200 patients respectively. None were from OHSU.

### **3. HITECH Notice of Proposed Rulemaking for Accounting of Disclosures:**

In May of 2011 the Department of Health and Human Services released a Notice of Proposed Rulemaking for the HITECH Act regarding new rules for the Accounting of Disclosures. HIPAA currently includes a requirement that upon request of a patient, a health care provider such as OHSU provide an accounting of the disclosures it has made of the patients health information. These proposed rules reduce the accounting period from six years to three years, and include a new patient right to an access report identifying individuals who have accessed their patient record on certain systems. The proposed rules are intended to provide more transparency into how the electronic medical record is accessed and used by the provider. These new requirements involve significant new administrative/financial undertakings by providers. OHSU has submitted comments regarding these proposed rules and we are expecting the final rule to be published in early 2012.

### **4. Oregon Health Information Technology Oversight Council (HITOC):**

At the state level, HITOC is charged with setting goals and developing a strategic health information technology plan for Oregon. The citizen members of this statutory committee are appointed by the Governor and confirmed by the Oregon Senate. OHSU is represented on the HITOC, on the Legal and Policy Workgroup and the Technology Workgroup. The HITOC has recently started developing processes related to health information exchange by proposed rulemaking to meet the requirements of the National Health Information Exchange Privacy & Security Framework which is a product of the U.S. Department of Health and Human Services. A HITOC Consent Implementation Subcommittee is planning to publish proposed rules in the first half of 2012 related to electronic health information exchange in Oregon.

## **B. OHSU Initiatives**

### **1. Response to National and State Picture:**

- a. The OHSU Integrity Office, in collaboration with OHSU's Information Technology Group, commenced the OHSU Information Security Initiative. The initiative is intended to decrease breach risk for unauthorized disclosure of health information. The initiative will:
  - i. Encrypt laptop and desktop computers beginning January 2011; and
  - ii. Activate security controls on handheld devices that access OHSU information.
- b. The OHSU Integrity Office reviewed and facilitated changes to comply with security and privacy requirements for the HITECH Act, and "meaningful use"<sup>1</sup> of OHSU's electronic health record;

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<sup>1</sup> "Meaningful use" is a concept employed in the HITECH ACT in the context of incenting providers to utilize electronic health record technology in a meaningful way to help improve the quality, safety, and efficiency of patient care.

- c. Participate in the Oregon HITOC consent subcommittee related to patient consent for electronic health information exchange;
- d. The OHSU Integrity Office continues to refine documentation and reporting of OHSU privacy and security incidents to promote effective risk mitigation.

## **VII. Audit & Advisory Services**

### **A. National Picture**

#### **1. Higher Education Audits:**

Federal agencies continue to emphasize the importance of effective internal audit programs. In cases where institutions have been fined or sanctioned for compliance failures, the requirements of corporate integrity agreements imposed by the government include internal audit capacity and function. Current “hot topics” identified by audit organizations and federal agencies include:

- a. Research compliance (human and animal subjects, grant compliance, effort reporting, ARRA fund compliance);
- b. Information technology and security issues;
- c. Employee relationships that may trigger conflict of interest issues;
- d. Procurement card use and oversight;
- e. HITECH/Business Associates issues;
- f. Controlled substance records;
- g. Capital construction projects;
- h. Hospital and clinical billing and receivables; and
- i. Charge capture.

### **B. OHSU initiatives**

#### **1. Response to National Picture**

- a. Audit Areas: OHSU’s Audit and Advisory Services program is completing its eighth year of incorporation into the Integrity Office. In calendar year 2011, Audit and Advisory Services (A&AS) participated in 22 projects, several of which relate to the above items of national interest. The process of developing an annual plan for subsequent year audits includes careful analysis of information from the national picture, review of areas that A&AS has audited within the past two years, internal assessments of the risk environment, and judicious allocation of audit resources by the Audit and Advisory Services Committee.

#### **2. Other Initiatives**

- a. Continuous Auditing: An evolving regulatory environment has made the implementation of electronic audit systems essential for an effective audit program. Audit and Advisory Services has fully deployed such a software program during CY 2011 to perform audit analytics and continuous auditing techniques. This program is

designed to identify errors and potential fraud and analyze entire data populations for anomalies, control deficiencies, and emerging risks. The benefits of implementing continuous auditing are realized through timely identification and correction of errors, increasing the efficiency of limited audit staff resources, and creating a stronger internal control environment across the OHSU enterprise. In its first project using this software program, A&AS staff identified \$99,449 in duplicate payments and recouped it.

- b. Staffing: The department ended calendar year 2011 with 2.6 FTE (down from 5.5 FTE in CY08). We anticipate the Audit Manager returning from military duty in early 2012. All current auditors hold multiple certifications, including Certified Internal Auditor, Certified Fraud Examiner, and Certified Public Accountant.
- c. Response to Review by Institute of Internal Auditors (IIA). OHSU engaged the Institute of Internal Auditors (IIA) to conduct an assessment of OHSU's Internal Audit Program ("Program"). The majority of findings were positive particularly as it concerns the conduct of audits, the nature of the audits and the Program's planning, the performance of audits, communication of results, the monitoring of progress against the audit results, resolution of acceptance of risks, staff qualifications, how the Program is regarded by stakeholders and the Program manual. Management has responded to the few concerns identified by the assessment to address the concerns to the satisfaction of OHSU leadership.

## **VIII. Integrity Education**

### **A. National Picture**

#### **1. Periodic Education:**

The Office of the Inspector General, the Office for Civil Rights, the National Institutes of Health, and other federal agencies continue to study and define the elements of an effective compliance program. Education is an essential element; it must be continuous, effective, and documented. Past approaches of delivering education modules via web-based or other computerized methods are being questioned. The NIH now requires a minimum of eight hours of live classroom education for the receipt of certain types of grants.

### **B. OHSU Initiatives**

#### **1. Response to National Picture**

- a. Periodic Education: In 2010 the OHSU Integrity Office implemented significant updates to the periodic integrity education system adding modules on biosafety and animal research. The OHSU Research Development and Administration Office has

taken the lead in addressing the new NIH requirements for live education and several education efforts in Integrity Program areas now include live approaches.

b. Education Summary Report (through 10/31/11):

	Total Learners	Completed Learners	Percent Compliant
<b>HIPAA - Privacy and You</b>			
All Employees	13813	13745	99.51
All Students	3178	3098	97.48
<b>Respect at the University</b>			
All Employees	13809	13737	99.48
All Students	3175	3071	96.72
<b>Information Security</b>			
All ITG Employees	233	232	99.57
<b>Hospital Compliance</b>			
Required Employees	5938	5923	99.75
<b>Fraud Awareness</b>			
Required Employees	784	777	99.11
<b>Integrity Education Booster</b>			
All Employees	13583	13008	95.77
All Students	3160	2521	79.78

## IX. Environmental Health & Radiation Safety

### A. National & State Picture

#### 1. Pharmaceutical Waste:

High profile discussions of pharmaceutical wastes found in public waterways have created concern about drinking water sources. Proposed revisions to long-unchanged Federal Environmental Protection Agency rules on pharmaceutical waste management could affect the way health care institutions manage waste streams and likely will involve increased monitoring and costs associated with disposal practices.

#### 2. OHSU/PSU Strategic Partnership:

In connection with the strategic partnership efforts of OHSU and Portland State University (PSU), OHSU has agreed to PSU's engaging on a part time basis, the

services of the Director of a portion of OHSU's Environmental Health and Radiation Safety (EHRS) Department . This collaboration allows for a leveraging of resources.

## **B. OHSU Initiatives**

### **1. Response to National & State Picture:**

Pharmaceutical Waste: EHRS is proactively monitoring potential regulatory changes to the management of pharmaceutical waste through direct interaction with the responsible regulatory community and national service providers. EHRS has also teamed up with the OHSU Pharmacy to assess current waste management practices. Our goal is to position OHSU to quickly and efficiently respond to new regulatory and/or best practices.

### **2. OHSU/PSU Strategic Partnership:**

In connection with the strategic partnership efforts of OHSU and Portland State University (PSU), OHSU has agreed to PSU's engaging on a part time basis, the services of the Director of OHSU's Environmental Health and Radiation Safety (EHRS) Department . As a result, John W. Burnham, Ph.D. recently accepted the part-time position of Assistant Director for Environmental Health and Safety at PSU while continuing to work part time at OHSU EHRS. This arrangement will allow the safety and environmental programs at both schools to explore existing programs, processes and policies with the ultimate goal of implementing best practices across both institutions.

## **X. Glossary of Acronyms**

<b>AAALACi:</b>	Association for the Assessment and Accreditation of Laboratory Animal Care, International. This is one of several national associations that oversee compliance with animal research regulations.
<b>A&amp;AS:</b>	OHSU's Audit and Advisory Services (internal audit) department.
<b>ANPRM:</b>	Advance Notice of Proposed Rule-Making. As used in this report, the term refers to the notice filed by the Office for Human Research Protections (OHRP) and U.S. Food and Drug Administration (FDA), proposing revisions to Common Rule.
<b>ARRA:</b>	The American Recovery and Reinvestment Act of 2009.
<b>CMS:</b>	Centers for Medicare and Medicaid Services
<b>EHRS:</b>	OHSU's Environmental Health and Radiation Safety Department
<b>FDA:</b>	The U.S. Food and Drug Administration

- HDI:** HealthDataInsights. This is the vendor that has contracted with the Centers for Medicare and Medicaid Services to perform all hospital billing audits under the recovery audit contractor (RAC) program.
- HIE:** Health Information Exchange.
- HIPAA:** The Health Insurance Portability and Accountability Act. HIPAA is divided into three rules related to information privacy, information security, and transaction and code sets.
- HIS:** The OHSU Health Information Services department
- HITECH:** Health Information Technology for Economic and Clinical Health
- HITOC:** Health Information Technology Oversight Council. This is a state-level program, charged with setting goals and developing a strategic health information technology plan for Oregon.
- IDE:** Investigational Device Exemption. This is a category provided by the FDA for investigational devices that are not yet approved for routine clinical use.
- IPOC:** Integrity Program Oversight Council. This is the OHSU Board of Directors-level committee charged with oversight of the integrity program.
- IRB:** Institutional Review Board. This is the committee responsible for review and approval of all human subjects' research at OHSU.
- ITG:** OHSU's Information Technology Group
- IVD:** In vitro diagnostics. The term, as used in this report, refers to experimental genomic and proteomic microarray tests performed in clinical trials and requiring FDA oversight.
- MAC:** Medicare Area Contractor. This is the vendor that has contracted with the Centers for Medicare and Medicaid Services to perform all hospital billing audits under the Medicare Audit Contractor (MAC) program.
- NIH:** National Institutes of Health
- OCR:** Office for Civil Rights. This is the federal office that oversees compliance with the Health Insurance Portability and Accountability Act (HIPAA).
- OHRP:** Office for Human Research Protections. This is the primary federal office that oversees human subject's research compliance.
- OIG:** Office of Inspector General of the U.S. Department of Health and Human Services.

- ORIO:** The OHSU Research Integrity Office
- PHI:** Protected Health Information
- PHS:** U.S. Public Health Service
- PSU:** Portland State University
- RAC:** Recovery Audit Contractor. This is the program initiated by the Centers for Medicare and Medicaid Services to contract with private audit firms to perform audits of hospital and professional fee billing.



# OHSU Integrity Program

## 2011 Annual Report

Presented by: Ronald G. Marcum, MD Interim Chief Corporate Integrity Officer  
Date: March 20, 2012

# Purpose of this presentation

- Support oversight responsibilities
- Update knowledge base
- Facilitate duty of care obligations

# Environment

- Heavily regulated
- Voluminous and complex rules that increase risk from non-compliance
- Increasing audit activity
- Increasing fraud, criminal and civil monetary penalties
- Risk of exclusion of health care providers from participation in federal health care programs

# Program Structure

- Chief Integrity Officer oversees Corporate and Research Integrity:
  - Clinical Billing Compliance
  - Information Privacy and Security
  - Internal Audit & Advisory Services
  - Integrity Education
  - Environmental Health & Radiation Safety
  - Conflict of Interest
  - Human Research Protection Program
  - Animal Care and Use Program
  - Institutional Biosafety

# Program Structure

- Goals
  - Provide an effective compliance program
  - Establish standards and processes
  - Mitigate compliance risk and vulnerabilities
  - Align with the OHSU Strategic Vision
- Review
  - Integrity Program Oversight Counsel (IPOC) – quarterly meetings and oversee the Program and risk management
  - Finance & Audit Committee - biannual review
  - OHSU Board of Directors – annual review

# Program Structure

- Other committees Advisory and Operational
  - Information Security and Privacy Committee (ISPC)
  - Clinical Compliance Committee
  - Audit & Advisory Services Committee
- Limitations
  - Continually changing regulatory landscape
  - Resource limitations (people and funding)
  - Continually changing and costly technology

# Program Structure

- Risk determination using standard assessment protocol
  - Determine the scope of the risks
  - Determine vulnerabilities
  - Prioritize risk based on OHSU specific data
  - determine controls/likelihood
  - Balance business needs and compliance risk to determine appropriate mitigation strategy
- Provision of resources informed by legal requirements, business needs and risk tolerance

# Operation of Integrity Program

- Collaboration
- Code of Conduct
- Policies and Procedures - creation and adaptation
- Integrity Education and Training
- Evaluation of the Integrity Program
  - Internal and External reviews auditors and regulators
  - Report responses to findings

# Operation of Integrity Program

- Clinical Billing – RAC, MAC, Non-RAC, targeted
- Research – animal, human subjects
- External regulatory reviews
- Complaints and Investigations
- Whistleblower protections

# Operation of Integrity Program

- Reporting systems for potential violations
  - Hot line
  - Direct calls
  - Monitoring
  - Risk assessments
  - Investigations
- Accountability established
- Appropriate sanctions

# Areas of Program Focus

- Clinical billing
- New programs
  - Knight Biolibrary
  - Export Control Program
- Information loss – security and confidentiality
  - Patient
  - Research data

# Areas of Program Focus

- Conditions of Participation
- Conflict of Interest – Corporate, Clinical, Research
- Regulatory landscape – continuous change

# Questions?

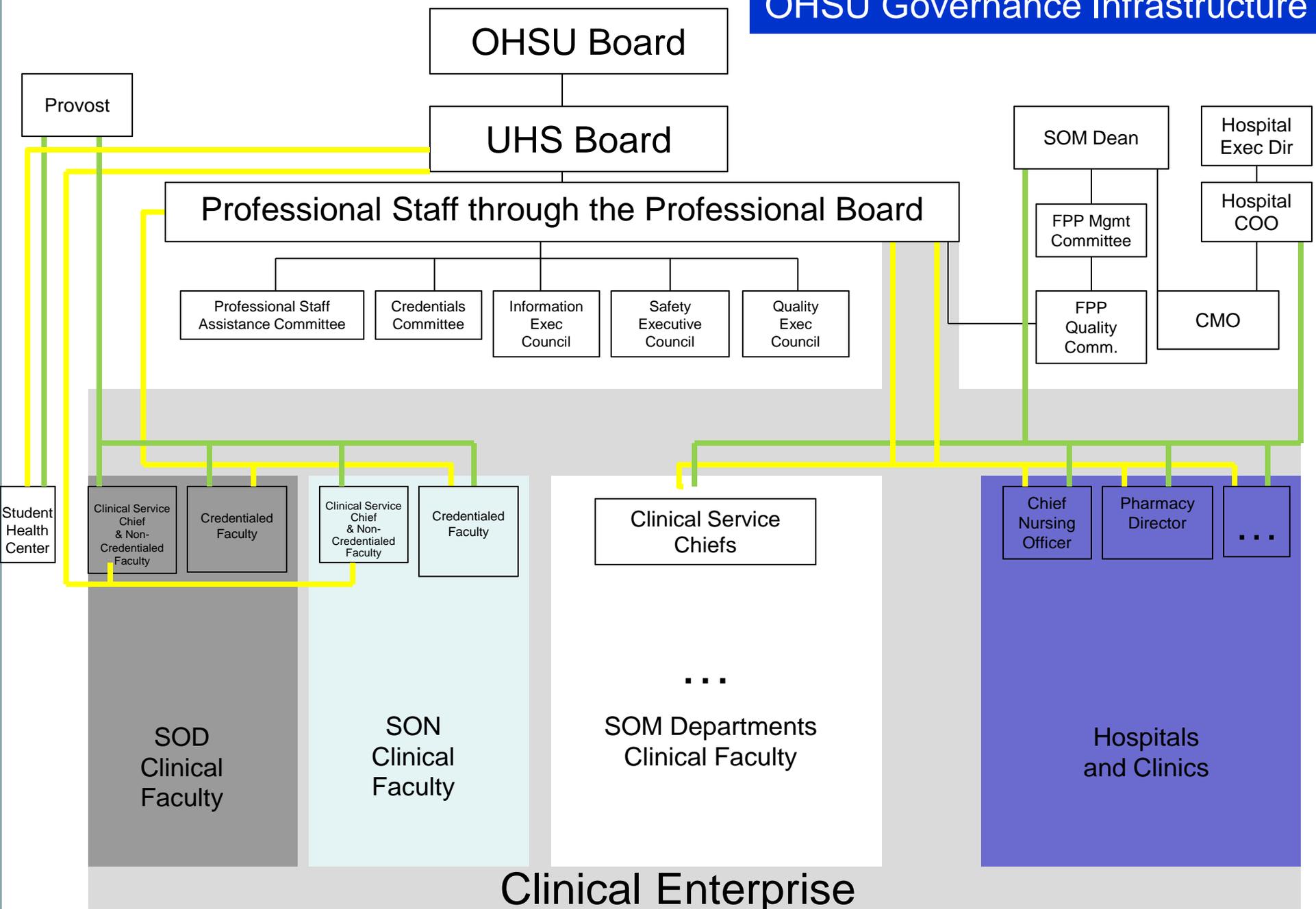
- Thank you



**OHSU Board Meeting  
March 20, 2012  
OHSU Healthcare Annual Quality and  
Safety Report**

# Performance Excellence at OHSU

- 1. Governance Structure for Quality and Safety**
- 2. Performance Improvement Infrastructure**
- 3. Alignment**
- 4. Measurement, Data, & Information Systems**



## Clinical Enterprise

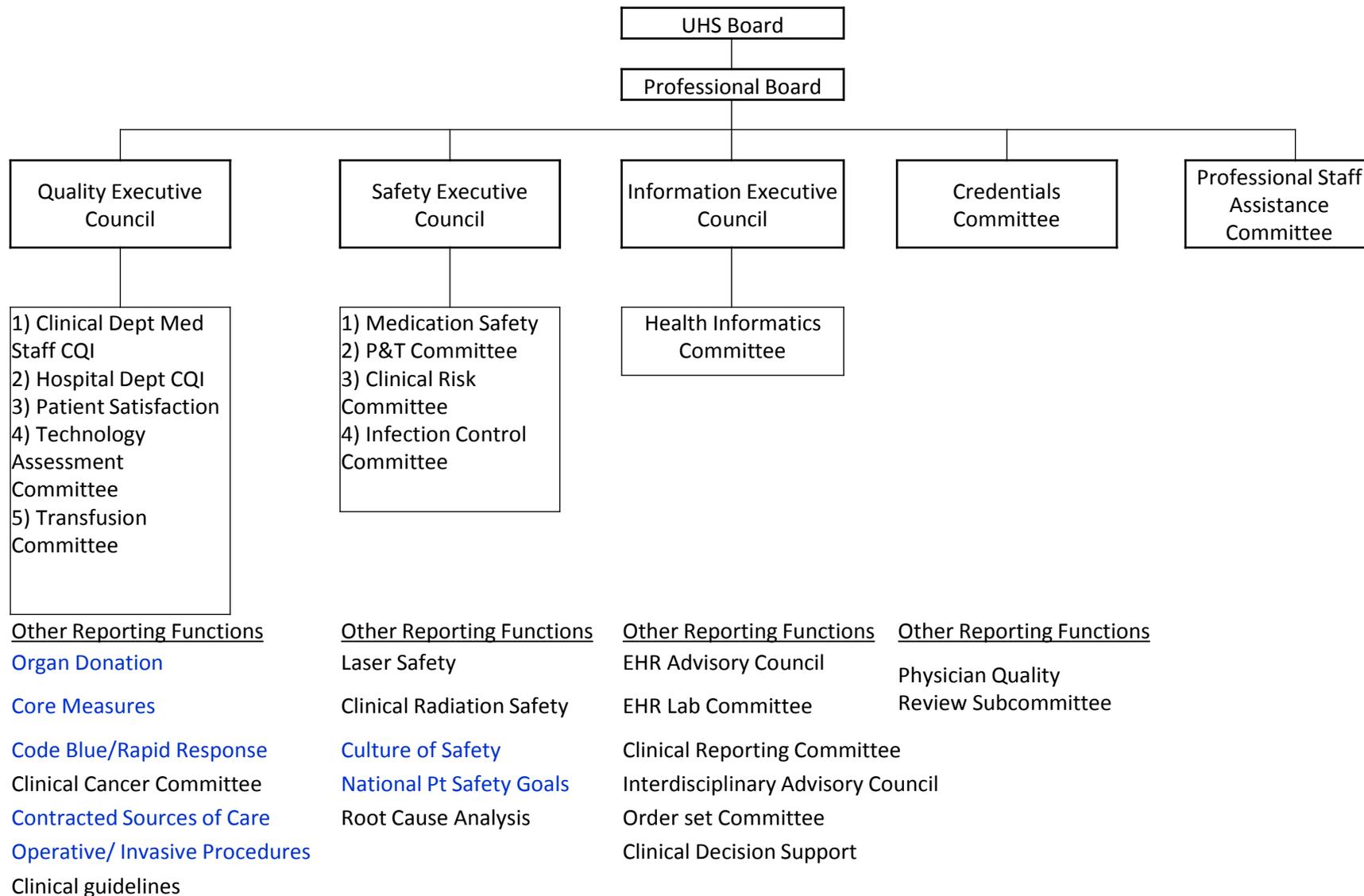
— = quality accountability  
— = employment/operational performance accountability

## OHSU Professional Staff Committee Structure, March 2012

Document in Bylaws

Org/Functions Manual

Functions within Council Charter



NOTES: Only the committees directly linked to the organizational chart are would be documented as "formal committees" of the medical staff within the Bylaws supporting document (Organization and Functions Manual). Committees and reporting topics that are being recommended to become hospital-based, and therefore reporting either through Hospital Administration or the Continuous Compliance Committee, are not reflected on this document. Blue items represent topics that are identified as necessary by The Joint Commission.

# OHSU Performance Excellence Systems

**Department Quality Infrastructure**

**Quality and Safety Management**

**Testing and Spread Infrastructure**

**Inpatient  
90 Day Plans**

**Outpatient  
Amb Collaborative**

**Methods**

**Lean**

**CAP**

**PSDA**

**6-Sigma**

**DMAIC**

**Measurement**

**External Databases**

**Internal Reporting: Datamarts, Dashboards**

**Clinical Informatics**

**Epic**

**Decision Support**

**Strategic CPD & Simulation**

# 90 Day Improvement Plans – FY12-13

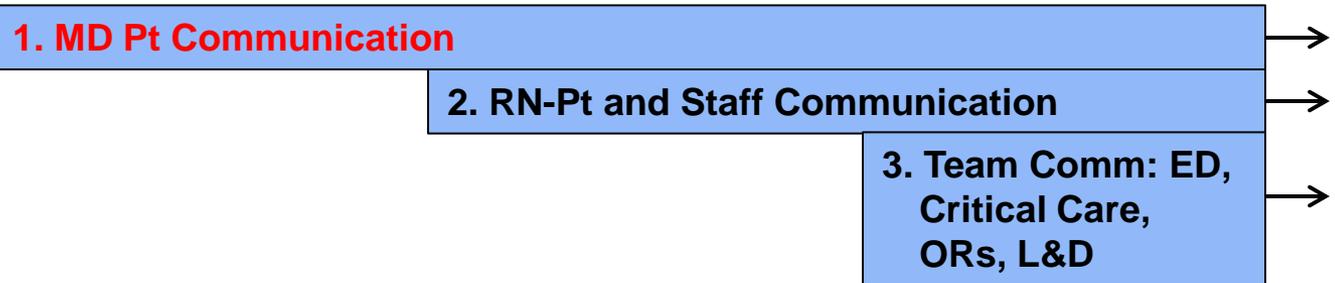
## 90 Day “Tests” – FY12 Q1

1. CHF d/c                      2. Foley mgmt                      3. VTE prophylaxis

FY12 Q2			Q3			Q4			FY 13 Q1		
Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep

1. Hand Hygiene Inpt	<b>1. CAUTI Prevention</b> <b>2. CLABSI Prevention</b>	1. Medication Rec 2. SSI Prevention	1. Outpt Hand Hygiene 2. Fall Prevention
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Communication Series 



# Performance Excellence at OHSU

- 1. Governance Structure for Quality and Safety**
- 2. Performance Improvement Infrastructure**
- 3. Alignment**
- 4. Measurement, Data, & Information Systems**

# Alignment

## OHSU Healthcare

- Professional Staff: ProBoard, QEC and SEC
- Quality and Safety Mgmt Dept
- Nursing
- Pharmacy

Assess quality gaps and needs, drive quality and safety objectives

Align

## School of Medicine

- Clinical Departmental Quality Infrastructure
  - Medical Directors for Quality
  - M&M, Peer Review
  - Residency Programs (Graduate Medical Education)
- Continuing Medical Education Program

# University HealthSystem Consortium (UHC)

- **Trusted data source** compares AMC, quarterly and annual risk adjusted outcomes
- **Key reports**
  - Quality and Accountability Scorecard → Our key self-assessment measurement set
  - Clinical Outcomes Report
    - By **department**
  - Quality and Safety Management Report
    - By **procedure or complication**



## 2011 Quality and Accountability Performance Scorecard

### Oregon Health & Science University (60)

This document presents the measures evaluated in the 2011 UHC Quality and Accountability ranking. This scorecard provides a comparison of your organization's performance with that of other academic medical centers. The data were obtained from existing UHC data resources, including the Clinical Data Base (Q3 2010-Q2 2011), and Core Measures Data Base (Q2 2010-Q1 2011), as well as HCAHPS data from the Hospital Compare Web site (Q4 2009-Q3 2010).

The goal of the Quality and Accountability ranking is to assess organizational performance across a broad spectrum of high-priority dimensions of patient care. The 2011 scoring and ranking cover the domains of mortality, effectiveness, safety, equity, patient centeredness and efficiency using measures developed by national organizations or the federal government.

<b>Overall Composite Performance</b>	<b>Rating</b>	<b>Composite Score</b>	<b>Top-Performer Score</b>	<b>Group Median</b>
<b>Overall</b> (Based on Clinical Domain Performance)	★★★	<b>61.7</b>	<b>72.0</b>	<b>63.5</b>
<b>Clinical Domain Performance</b>	<b>Rank (* denotes tie)</b>	<b>Domain Score</b>	<b>Top-Performer Score</b>	<b>Group Median</b>
<b>Mortality (25%)</b>	<b>20*</b>	<b>64.1%</b>	<b>74.1%</b>	<b>58.6%</b>
Includes UHC O/E mortality rate for the following selected product service lines: bone marrow transplant, burns, cardiology, cardiothoracic surgery, cardiac surgery, thoracic surgery, gastroenterology, gynecology, gynecologic oncology, heart/lung transplant, HIV, kidney/pancreas transplant, liver transplant, medical oncology, medicine general, neurology, neurosurgery, obstetrics, orthopedics, otolaryngology, plastic surgery, rheumatology, spinal surgery, surgical oncology, surgery general, trauma, urology, vascular surgery, and ventilator support.				
<b>Effectiveness (25%)</b>	<b>90*</b>	<b>65.0%</b>	<b>95.0%</b>	<b>77.5%</b>
Includes all-cause readmission rate within 30 days after discharge (excluding chemotherapy, dialysis, obstetric delivery, radiation therapy, and rehabilitation and psych (within 1 day) from numerator and OB, neonatology and normal newborn service lines and death at 1st admit from the denominator) and Joint Commission Hospital Core Measures composite scores for AMI, HF, PN, and SCIP: percentage of patients who received all of the care they were eligible to receive.				
<b>Safety (25%)</b>	<b>68*</b>	<b>52.1%</b>	<b>75.0%</b>	<b>56.3%</b>
Includes PSI metrics: PSI-3 pressure ulcer, PSI-6 iatrogenic pneumothorax, PSI-7 central line associated BSI, PSI-9 postoperative hemorrhage and hematoma, PSI-11 postoperative respiratory failure, PSI-12 postoperative pulmonary embolism or deep vein thrombosis.				
<b>Equity (5%)</b>	<b>88*</b>	<b>91.7%</b>	<b>100.0%</b>	<b>100.0%</b>
Includes Joint Commission Hospital Core Measures composite scores for AMI, HF, PN, and SCIP, testing for statistically significant differences in outcomes in 3 equity-based dimensions: gender (male vs. female), race (white vs. nonwhite), and socioeconomic status (Medicaid, self-pay, uninsured, and charity combined vs. all others).				
<b>Patient Centeredness (10%)</b>	<b>46*</b>	<b>56.3%</b>	<b>76.6%</b>	<b>56.3%</b>
Includes 10 HCAHPS questions on nurse communication, doctor communication, pain management, communication about medications, cleanliness and quietness, responsiveness of staff, and discharge information and overall rating of the hospital averaged as a composite.				
<b>Efficiency (10%)</b>	<b>23*</b>	<b>62.5%</b>	<b>75.0%</b>	<b>56.3%</b>

LOS O/E and direct cost O/E for following selected service lines: cardiology, gastroenterology, medical oncology, general medicine, neurology, general surgery, neurosurgery, cardiac surgery and thoracic surgery. Cases within the above service lines with 1 day LOS and an MS-DRG in the following list are excluded: 069, 190, 191, 192, 291, 292, 313, 391, 392, 223, 225, 226, 227, 242, 243, 244, 245, 246, 248, 249, 251, 259, 261 and 262.

# UHC Quality and Accountability Scorecard

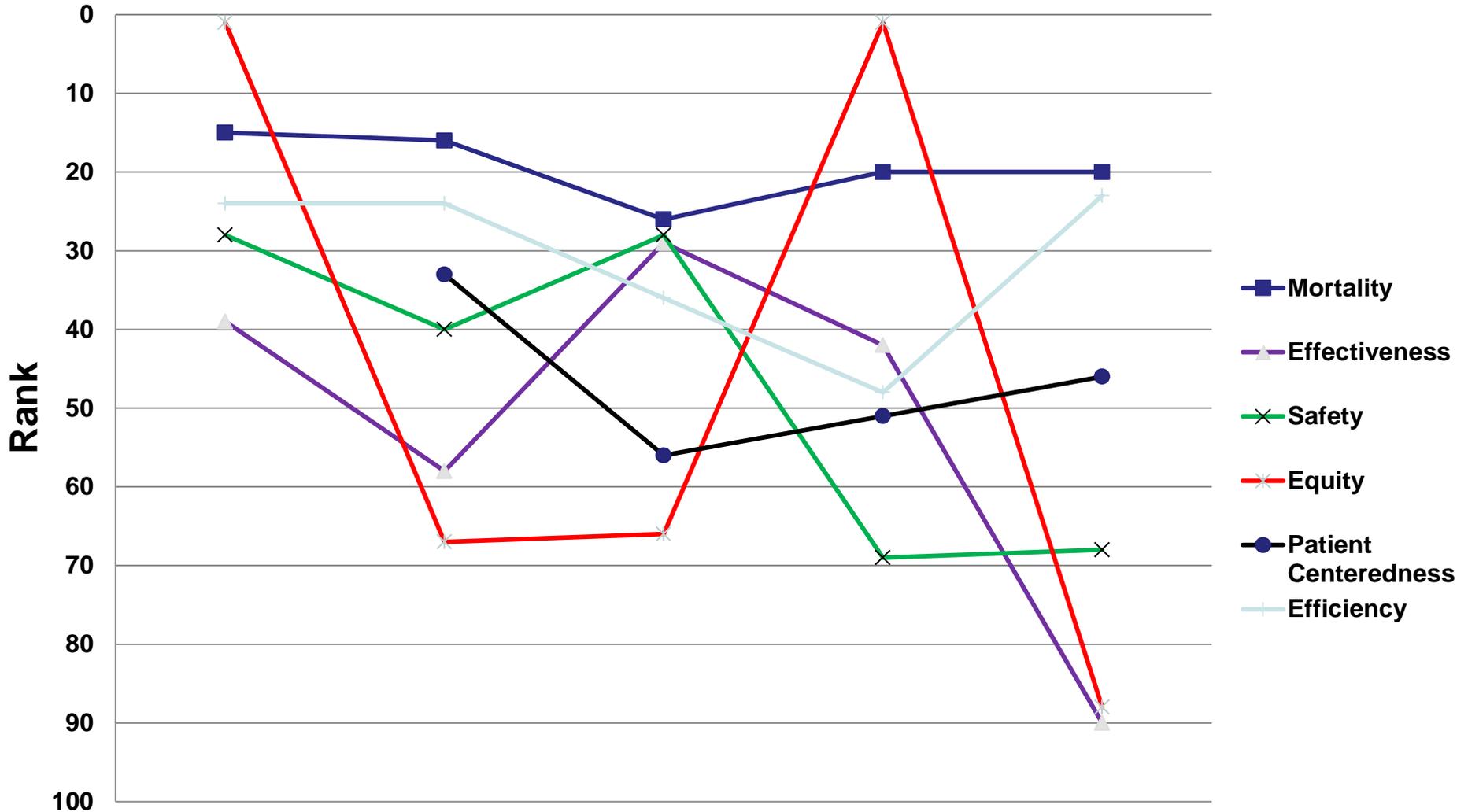
2007

2008

2009

2010

2011



# UHC Clinical Outcomes Report

## Oregon Health & Science University Jul - Sep 2011 (Q3) UHC Teaching Hospitals

	Jul - Sep 2011 (Q3)						Oct 2010 - Sep 2011 (recent year)					
	Relative Performance	Denom (Cases)	Obs Mort(%)	Obs/Exp Ratio	UHC Median	Rank	Relative Performance	Denom (Cases)	Obs Mort(%)	Obs/Exp Ratio	UHC Median	Rank
<b>Summary</b>												
Post-Surgical	⊙⊙	2,424	1.11	0.52**	0.88	1/111	⊙	9,629	1.65	0.74**	0.92	13/112
Quality and Accountability Aggregate	⊙	6,958	1.57	0.72**	0.91	18/111	⊙	26,863	1.82	0.82**	0.95	24/114
Total Inpatient	⊙⊙	7,961	1.39	0.70**	0.92	11/112	⊙	30,693	1.67	0.82**	0.96	24/114
<b>Service Line</b>												
BMT	⊙⊙	56	0.00	0.00	0.52	2/ 62	⊙	194	3.09	0.70	0.80	28/ 67
Burns	⊙!	3	0.00	0.00	0.91		⊙!	11	0.00	0.00	1.06	
Cardiology	⊙	369	3.52	1.07	0.97	80/113	⊙	1,421	3.38	1.08	1.00	77/116
Cardiac Surgery	⊙	146	2.05	0.77	0.89	43/100	⊙	561	1.96	0.74	0.91	37/104
Thoracic Surgery	⊙⊙	94	0.00	0.00	0.78	2/109	⊙⊙	359	1.11	0.40	0.89	12/115
Gastroenterology	⊙⊙	443	0.45	0.30	0.77	9/114	⊙⊙	1,710	0.94	0.50**	0.92	6/117
Gynecology	⊙⊙	79	0.00	0.00	0.00	57/ 87	⊙⊙	250	0.00	0.00	0.00	50/ 91
Gynecology/Oncology	⊙⊙	19	0.00	0.00	0.00	40/ 86	⊙⊙	80	0.00	0.00	0.76	17/ 88
Heart Transplant or Implant of Heart Assist System	⊙	8	12.50	0.83	0.82	28/ 53	⊙	51	3.92	0.45	0.78	16/ 57
HIV	⊙	14	7.14	1.48	0.83	65/ 82	⊙⊙	59	1.69	0.31	0.98	8/ 92
Kidney/Pancreas Transplant	⊙⊙	24	0.00	0.00	0.00	34/ 57	⊙⊙	79	0.00	0.00	0.00	32/ 58
Liver Transplant	⊙⊙	10	0.00	0.00	0.00	30/ 49	⊙⊙	41	0.00	0.00	0.54	8/ 50
Lung Transplant					0.00						0.00	
Med Oncology	⊙	375	3.20	0.83	0.94	45/114	⊙	1,452	2.82	0.79	0.96	37/117
Medicine General	⊙	1,371	2.19	0.92	0.90	63/114	⊙	5,639	2.18	0.97	0.99	53/117
Neonatology	⊙	239	0.84	0.53	0.68	34/101	⊙	927	1.73	0.96	0.71	77/105
Neurology	⊙	350	3.14	0.83	0.91	45/114	⊙	1,313	2.74	0.84	0.97	34/116
Neurosurgery	⊙	280	2.50	0.52	0.81	28/110	⊙	1,061	3.49	0.67*	0.85	29/115
Obstetrics	⊙⊙	683	0.00	0.00	0.00	42/ 99	⊙⊙	2,573	0.00	0.00	0.61	25/102
Orthopedics	⊙⊙	321	0.00	0.00	0.78	9/104	⊙	1,303	0.38	0.80	0.75	60/104
Otolaryngology	⊙⊙	155	0.00	0.00	0.00	4/ 86	⊙	557	0.18	0.51	0.89	27/ 91
Plastic Surgery	▶	37	0.00	0.00	0.00	35/ 71	⊙	177	1.13	1.73	0.78	52/ 65
Rheumatology	▶	46	0.00	0.00	0.00	38/107	⊙	169	1.18	0.88	0.88	57/110
Spinal Surgery	⊙⊙	298	0.00	0.00	0.00	7/ 93	⊙⊙	1,174	0.00	0.00	0.69	2/ 95
Surg Oncology	⊙	55	1.82	1.10	0.83	52/ 85	⊙	238	1.26	0.52	0.92	19/ 90
Surgery General	⊙⊙	700	0.57	0.32*	0.78	4/114	⊙	2,842	1.30	0.72*	0.84	26/117
Trauma	⊙	733	2.59	0.68	0.99	20/113	⊙	2,371	3.42	0.90	1.01	40/116
Urology	⊙	170	0.59	1.36	0.91	75/110	⊙	721	0.28	0.56	0.80	35/111
Vascular Surgery	⊙	99	2.02	0.74	0.80	47/103	⊙	313	1.92	0.68	0.85	30/106
Ventilator Support	⊙	20	10.00	0.77	1.12	22/114	⊙	144	18.06	0.96	1.08	33/117

### Legend

- Substantially Worse than Target Range Performance > 90th percentile of peer group
- ⊙ Worse than Target Range Performance > 50th percentile of peer group
- ⊙ Within Target Range Performance <= 50th percentile of peer group
- ⊙⊙ Substantially Better than Target Range Performance < 10th percentile of peer group
- ! Interpret with Caution Low volume, excluded from top-10

\* Significant difference from expected at .05 level of significance

- ▶ Quality Alert Warning Quality alert screening criteria triggered (only for current quarter)

#### Quality Alert Screening Criteria:

- Most recent 8 quarters mortality higher than expected and one of the most recent 4 quarters has O/E Ratio >= 1.4
- Any 2 data points in the most recent 4 quarters have O/E Ratio >= 1.4

## **An Example**

# **Reducing Central Line Associated Blood Stream Infections (CLABSIs)**

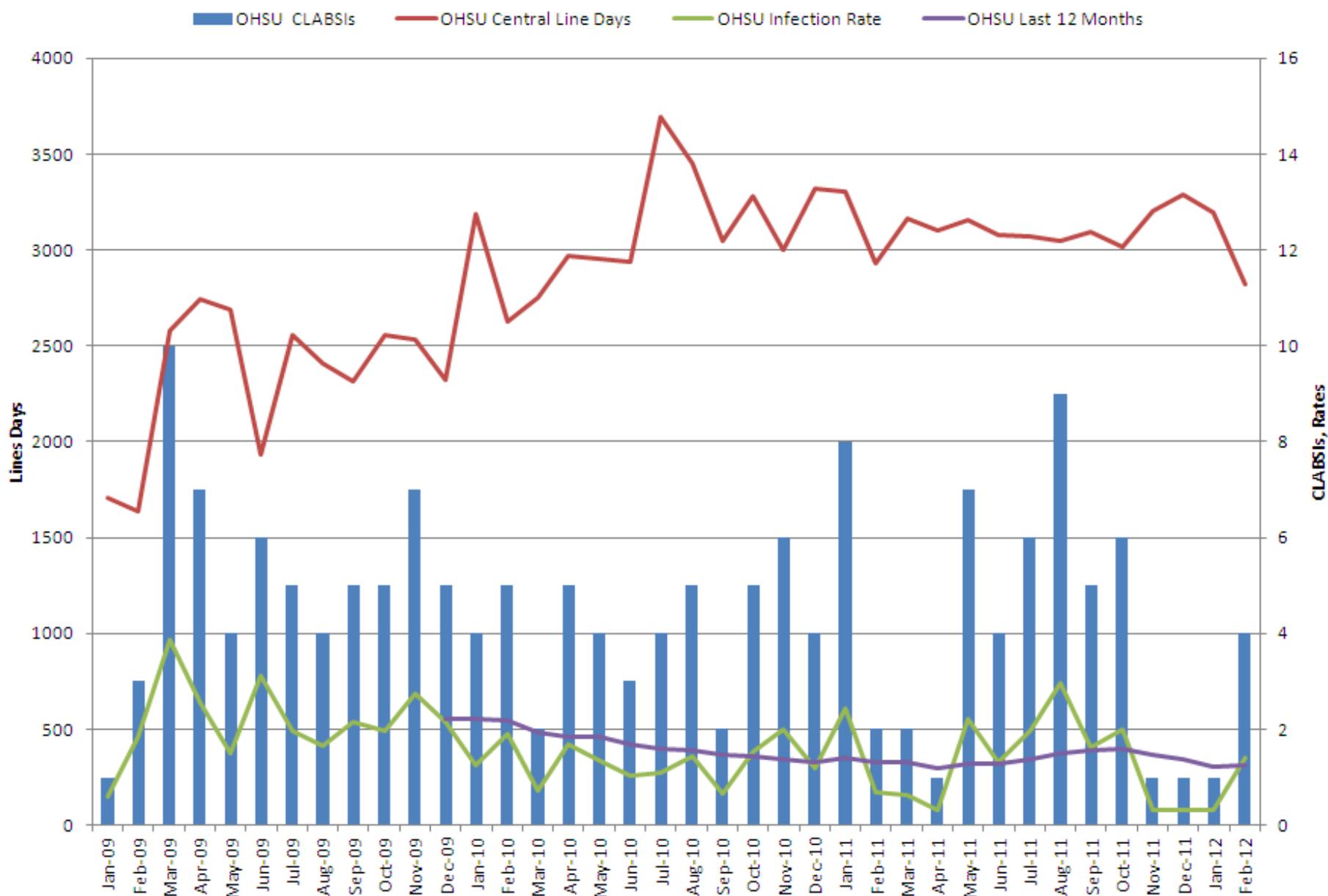
# CLABSI Reduction

Successful implementation of evidenced based guidelines for central line insertion, maintenance and monitoring can substantially reduce CLABSIs.

**Why:** CLABSIs causes preventable pt harm. OHSU reported 60 CLABSIs from Nov '10 – Oct '11. “Additional Cost” estimate ~\$20k/case (\$1.2M total), 9 days/case extra LOS (540 extra days total)

**Goal:** Eliminate CLABSIs

# OHSU CLABSI data since Jan, 2009



# CLABSI Rates (NHSN Reported)

Unit	Baseline (Nov'10- Oct'11)	2011 Target	Nov	Dec	Jan	Feb	Last 6 mo
12K (Medical ICU) Infections per 1,000 Line Days	1.58	0.8	0	0	0	0	0.00
8CSI (Surgical ICU) Infections per 1,000 Line Days	0.22	0.5	0	0	0	0	0.44
7A (Trauma ICU) Infections per 1,000 Line Days	3.61	0.7	0	0	0	0	2.68
7NSI (NeuroSurg ICU) Infections per 1,000 Line Days	1.02	0.3	0	0	0	0	0.00
13K (Adult Oncology) Infections per 1,000 Line Days	0.79	0.0	0	0	0	0	0.44
14K (Adult BMT/HM) per 1,000 Line Days	2.79	0.0	0	1.16	1.24	5.54	2.69
10S (Pediatric Hem/Onc) Infections per 1,000 Line Days	2.00	0.0	0	0	0	0	0.39
12A (DNCC) Infections per 1,000 Line Days	0.58	0.0	2.53	0	0	0	0.56
8NPI (Pediatric ICU) Infections per 1,000 Line Days	2.56	0.0	0	0	0	0	0.00

- **1 CLABSI in November**
- **1 CLABSI in December**
- **1 CLABSI in January**
- **4 CLABSI in February – case reviews scheduled for March 21.**
- **1 CLABSI so far in March (12A – DNCC)**

# In Progress



- 1. Establish KPI dashboards for all units and departments and push metrics out.**
- 2. Regular rounding on KPI Boards for unit-based improvement**
- 3. Improve dept infrastructure for quality, safety, service, and communication excellence**
- 4. Drive further alignment of departments and funding with strategic priorities**

# Oregon Health & Science University

## Corporate Responsibility and Health Care Quality

March 2012

The US Department of Health and Human Services, Office of the Inspector General, and American Health Lawyers Association has provided the following 10 questions for health system Boards of Directors to consider in their oversight of quality and safety. We address these questions in writing here and would be happy to discuss them in greater detail at the discretion of the OHSU and UHS Boards.

### **Overview of OHSU Healthcare Infrastructure for Quality Improvement and Oversight**

The OHSU Board of Directors is legally responsible for conduct of OHSU Healthcare and has delegated such responsibility through the OHSU President to the University Health System Board (“UHS Board”) to govern the clinical activities of OHSU Healthcare. The UHS Board is charged with responsibility (i) to ensure high quality and safety in all OHSU clinical activities, (ii) to ensure compliance with licensing and accreditation requirements of The Joint Commission, Centers for Medicare & Medicaid Services (CMS) and the State of Oregon Health Division, and (iii) to ensure that health care professionals practicing in the OHSU Healthcare are organized to effectively oversee the delivery of clinical care for purposes of ensuring quality and safety. In fulfilling these responsibilities, the UHS Board looks to the Professional Staff to oversee quality and safety in the delivery of patient care.

The attached diagrams depict the infrastructure related to the UHS Board and the Professional Board, described below.

Licensed independent professionals within OHSU Healthcare are organized as a “Professional Staff” that is represented by a multidisciplinary “Professional Board” made up of a mix of appointed and elected representatives as proscribed in our Bylaws. This includes, for example, several chairs of clinical departments from the OHSU School of Medicine, and the Executive Director and Chief Nurse Executive of OHSU Healthcare. The Professional Board’s role is to oversee quality and safety and guide improvement efforts.

Various councils and committees report to the Professional Board. Two key councils include the Quality Executive Council (QEC) and the Safety Executive Council (SEC). The QEC is a multidisciplinary group that oversees activities related to quality of care and establishes annual quality objectives. The SEC is a multidisciplinary group that oversees activities related to patient safety and establishes annual safety objectives..

- 1. What are the goals of the organization’s quality improvement program? What metrics and benchmarks are used to measure progress towards each of these performance goals? How is each goal specifically linked to management accountability?**

OHSU Healthcare's overall quality goal is to achieve consistent top quartile performance on the University HealthSystem Consortium's (UHC) Quality and Accountability Scorecard, in addition to achieving our annual quality and safety objectives as defined by the QEC and SEC. Combined, these quality and safety metrics are aligned with nationally stated priorities and defined benchmarks – they are available upon request.

QEC, SEC, and OHSU Healthcare leaders review our performance data, adverse events, regulatory changes, and national priorities in quality and safety to establish their priorities. These priorities are then presented to the OHSU Healthcare Administrative Team, QEC and SEC for approval. The resulting performance improvement priority recommendations are then submitted to the Professional Board and upon approval are presented to the UHS Board for adoption.

The Professional Board, QEC, and SEC are staffed by Chief Medical Officer's office including personnel in quality and safety management and the medical affairs office. Management actively participates on each of these committees, and quality improvement efforts are also reported to the OHSU Administrative Team regularly who hold joint accountability with the Professional Staff to achieve performance improvement objectives.

The Director of Quality and Safety Management, reporting to the Chief Medical Officer, holds responsibility for monitoring these priorities, using improvement teams with appropriate methodologies and metrics that measure project success. These data are reported monthly in a dashboard format to the QEC and SEC. Action plan recommendations from these councils are taken to the Clinical Departments, Faculty Practice Plan, OHSU Administrative Team, and/or Professional Board.

Resourcing of these priorities is done through the OHSU Healthcare capital and operating budget cycle.

**2. How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?**

Our measurement systems are well established through (i) our partnership with nationally recognized external data and analytic partners such as UHC and others, and (ii) internal systems based on our electronic health record and other databases. Improvement is guided by both nationally established and institutional priorities. OHSU has adopted several methodologies to drive performance improvement including, but not limited to, the use of the Change Acceleration Program (CAP), the basic testing of change via Plan-Do-Study-Act (PDSA) cycles, and Lean improvement.

Clinical leaders and management are involved in all aspects of our performance improvement efforts ranging from their oversight via participation on the Professional Board, QEC and SEC to their direct involvement in specific initiatives. On OHSU Healthcare's Administrative Team, the Chief Medical Officer (CMO) and Chief Nurse Executive (CNE) are the positions most directly responsible for leading performance

improvement efforts. They work together daily on performance improvement efforts, the CMO staffs the UHS board meeting, and the CNE is a frequent presenter and discussant at Board meetings.

Within the medical disciplines, Clinical Service Chiefs are responsible for building quality improvement infrastructure and driving performance improvement in their areas of clinical responsibility, working closely with Quality and Safety Management to accomplish this.

**3. How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?**

Our quality standards are well integrated into policies and operations consistent with regulations established by several national and local certifying bodies, including The Joint Commission, the Centers for Medicare and Medicaid Services, and the State of Oregon. These standards are continuously reviewed and updates implemented via our Regulatory Affairs office working in conjunction with OHSU Healthcare administration, managers, and front line staff via our Continuous Compliance Committee and other venues. Our multidisciplinary Continuous Compliance Committee meets monthly. Reports are provided to the UHS Board concerning responses to regulatory requirements and the requirements of various certifying bodies.

OHSU Healthcare maintains a set of policies and procedures that are updated on a three year review cycle. There are a set of 'regulatory required documents' that are mandated by regulatory bodies and a set of functional, health system wide policies. These documents are reviewed by a committee or council appropriate to the content of the policy. The OHSU Healthcare Policy Steering Committee reviews all of these documents; policy required by regulation is assigned a sponsor from the OHSU Administrative Team. Sitting in an advisory capacity to the OHSU Healthcare Policy Steering Committee is a representative from OHSU legal counsel. OHSU Legal counsel also chairs the OHSU (institution-wide) Policy Advisory Committee, a presence that assures congruence between university and OHSU Healthcare policies.

The annual priorities approved by the UHS Board are intended to drive OHSU Healthcare operational resource expenditures. Progress on priorities is monitored monthly through the QEC, SEC, and Administrative Team, and reported quarterly to the UHS board. Policies that support quality assessment and improvement processes are developed in various areas of the organization and approved by committees appropriate to the content of the policy.

Adherence to policy in clinical practice occurs through process and outcome metrics that are tracked and reported by the quality and safety programs. Variance in practice from established policy is monitored by professional peer review, by Best Practice teams in clinical service areas, and is reviewed by council and committee structures.

An example of the integration of quality and safety priority setting and policy is OHSU Healthcare's response to a National Patient Safety Goal established by The Joint Commission. Use of standardized, evidence based, care bundles in the prevention of Central Line Associated Blood Stream Infections has become clinical policy that is monitored in practice.

**4. Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?**

New OHSU Board members receive an orientation that includes an overview of their oversight responsibilities regarding healthcare quality and patient safety. New members of the UHS Governing Board are provided a formal orientation to their responsibilities as a Board member. This includes information about national trends in clinical quality and patient safety as well as data specific to Oregon and OHSU's performance. The new member is introduced to OHSU Healthcare's external data partners used to measure clinical quality and patient safety performance. This orientation is provided by OHSU Healthcare's Chief Operating Officer and Chief Medical Officer.

**5. What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement efforts?**

Critical to the Board's oversight of quality is an understanding of national trends and priorities, health policy changes, OHSU's measurement capabilities and meaning of the metrics, and much more. Quarterly UHS Board meetings contain a mix of informational and educational content along with specific performance metrics, assessments of performance gaps, and plans to drive performance improvement. We are moving toward delivering a standard set of reports to the UHS Board for their review, irrespective of whether or not they are discussed directly during Board meetings.

The UHS Board reviews performance metrics quarterly.

**6. How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?**

OHSU Healthcare Administration and our Regulatory Affairs office works in conjunction with OHSU Integrity program to fulfill regulatory requirements. The Integrity Program - in some institutions known as the corporate compliance program - addresses risks to integrity in a number of ways:

1. Risk analysis for information privacy and security; healthcare and professional billing; internal assessment and audit of identified high risk areas in various mission areas of the university, and relationships among providers than can compromise care, quality or payment mechanisms.
2. Based on the risk assessments results, corrective actions are implemented based on best practices and regulatory requirements.

3. Continuous assessment of reported incidents.
4. Education regarding identified risks and corrective actions is coordinated with healthcare and professional staff with on-line and face-to-face training
5. Hotline reporting to the Integrity Department regarding matters that relate to quality or patient safety is “triaged” to the Chief Medical Officer or designee.

The integrity of the medical record is critical to provide accurate data for assessment of the quality of patient care.

Environmental Health and Radiation Safety is a unit within the Integrity Office that is responsible for compliance relative to the facilities that encompass the “environment of care” including routine environmental threat assessments. Public Safety provides a yearly report on the Environment of Care to the UHS Board.

As pertains to patient safety and liability risk, the Chief Medical Officer, Patient Safety Officer, and key risk management personnel meet twice monthly. A part of their work is to review various risk management and safety data streams in order to design and implement risk prevention strategies.

**7. What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?**

Clinicians and staff can report safety concerns and errors via a number of mechanisms including the direct reporting to their manager, their department chair, the CMO or CNE, human resources, and the option for anonymous reporting through a secure Integrity Office system. Issues reported anonymously are reviewed by human resources, the integrity office, and CMO to decide who will manage each situation.

OHSU informs patients of their right to report any concern regarding patient safety or clinical quality that has not been adequately resolved to the Oregon Department of Human Services and The Joint Commission. OHSU’s Code of Conduct explains to all employees how they may report unresolved concerns without fear of retaliation.

Our primary reporting system for adverse events is the Patient Safety Network (PSN) which allows online reporting. Reports are reviewed daily by OHSU’s Manager of Patient Safety – applicable reports are reviewed with the pertinent managers who work with quality and safety management personnel on assessment and improvement activities. OHSU’s Code of Conduct establishes a non-retaliation environment in reporting concerns about clinical quality, patient safety, or medical error. In addition, the OHSU policy “Disclosures of Serious Events, Error, and Near Misses” serves as a framework for reporting adverse events and error in a non punitive environment.

Critical safety events undergo a root cause analysis followed by performance improvement activities. Sentinel events are reported immediately to OHSU Healthcare leadership including the Executive Director. After an investigation is performed, findings and corrective actions are reviewed with the SEC and OHSU Healthcare Administrative

Team. The SEC also establishes yearly performance improvement objectives which are the focus of a variety of improvement activities overseen by nursing, quality and safety management, and others.

Sentinel events are reported to and reviewed with the UHS Board at each meeting.

**8. Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?**

The appropriate staffing of OHSU's quality and safety staff is reviewed regularly and adjusted as needed by OHSU Healthcare leadership. OHSU clinical departments work directly with quality management and have been boosting their internal quality management capabilities through the establishment of physician quality leaders and the creation of a performance improvement plan in conjunction with quality management for instance.

The UHS Board approves our clinical quality and patient safety organizational priorities annually. Priorities are based upon performance reported from trusted data sources, national trends, regulatory requirements, or special cause needs.

Approved priorities are resourced in capital and operational funding by the OHSU Healthcare Administrative Team, and these efforts are operationalized through quality management via a number of improvement mechanisms as described herein.

**9. Do the organization's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?**

OHSU's activities in these areas meet national standards. That said, competency assessment and training, assessing quality of care within the credentialing process, and peer review are all areas of active continuous improvement within OHSU and nationally.

OHSU demonstrates commitment to clinical quality and patient safety in credentialing and privileging processes within our Medical Affairs Program, utilization of a Credentialing Committee for its oversight, and the Professional Board for coordination of these processes. Clinical service chiefs are responsible for the oversight of competency and ongoing training of their faculty, and to attestation as such within the re-credentialing process.

Peer review occurs within each clinical department including the use of methods such as Morbidity and Mortality conferences for instance. The use of administrative data from the University HealthSystem Consortium's (UHC) Clinical Data Base provides trusted, comparative data among teaching hospitals used to track outcome and process trends in clinical quality and safety.

**10. How are “adverse patient events” and other medical errors identified, analyzed, reported, and incorporated into the organization’s performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization’s liability exposure?**

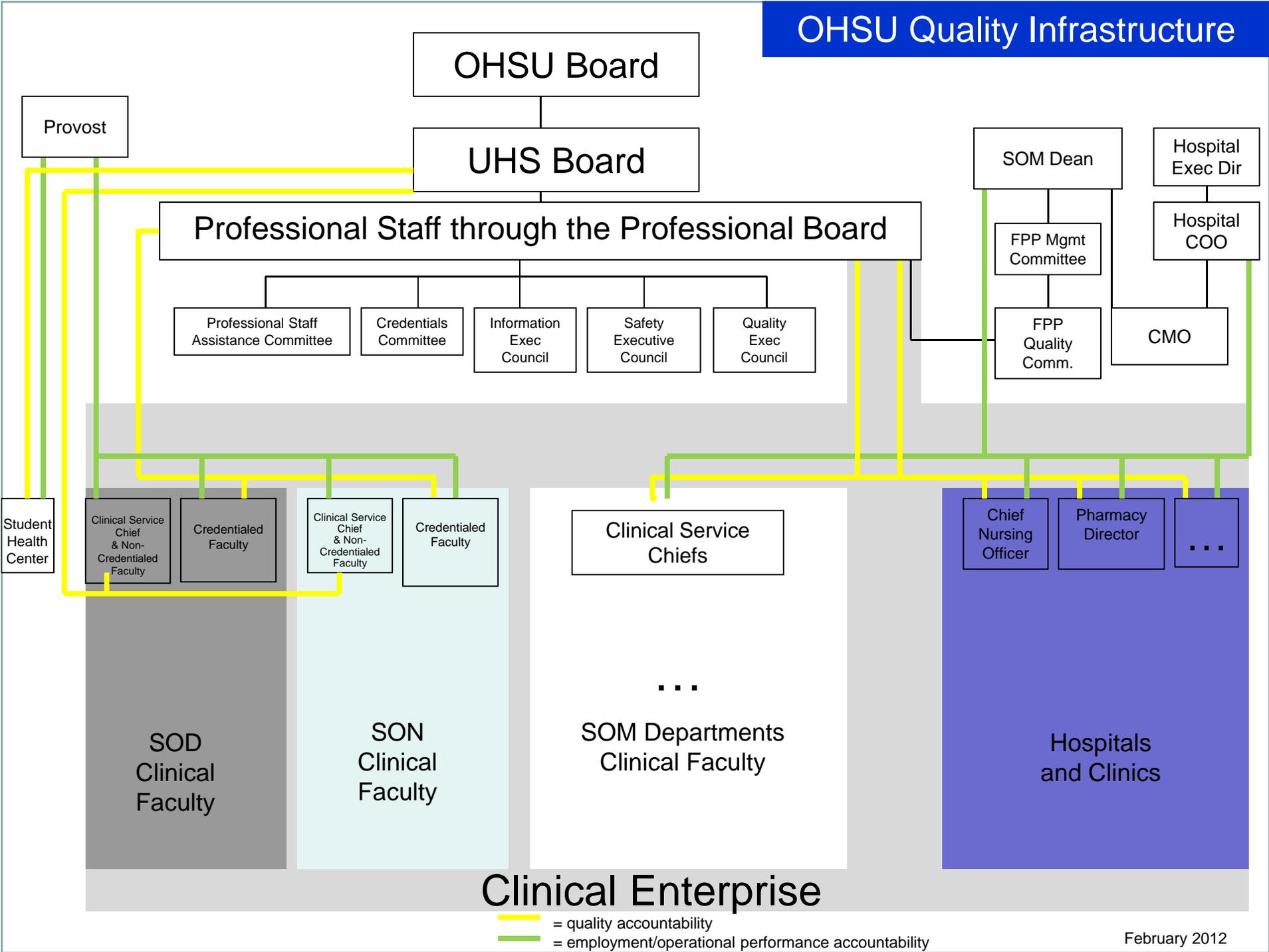
Please refer to Question 7. Quality and safety reporting and improvement initiatives and activities are discussed openly. Where particular areas of concern exist or a particular circumstance or occurrence is examined, it occurs within the peer review and quality improvement infrastructure described above. Because Oregon law protects the confidentiality of peer review activity, this allows for a dialogue and a rigorous examination of opportunities for improvement without subjecting the institution to liability. OHSU’s Clinical Risk Committee meets twice a month with the goal of continually assessing risk and planning risk reduction activities. The Director of Risk Management reports to the OHSU Healthcare CEO, and works closely with the CMO on issues of clinical risk.

OHSU Healthcare utilizes UHC’s Patient Safety Network for adverse event reporting. Adverse events are reviewed by an Incident Review Team bimonthly. Trend reports are provided to the OHSU Administrative Team and SEC.

The Professional Board is provided a report monthly and the UHS Board quarterly of all medical staff appointments. These appointments use peer review data in the privileging and credentialing processes that receives oversight by a Credentialing Committee.

OHSU continues to improve Ongoing Provider Practice Evaluation (OPPE) and Focused Provider Practice Evaluation (FPPE) processes as mandated by The Joint Commission. These processes are intended to evaluate privilege-specific competence of a practitioner as well as professional practice trends that impact quality of care and patient safety.

# OHSU Quality Infrastructure



## Clinical Enterprise

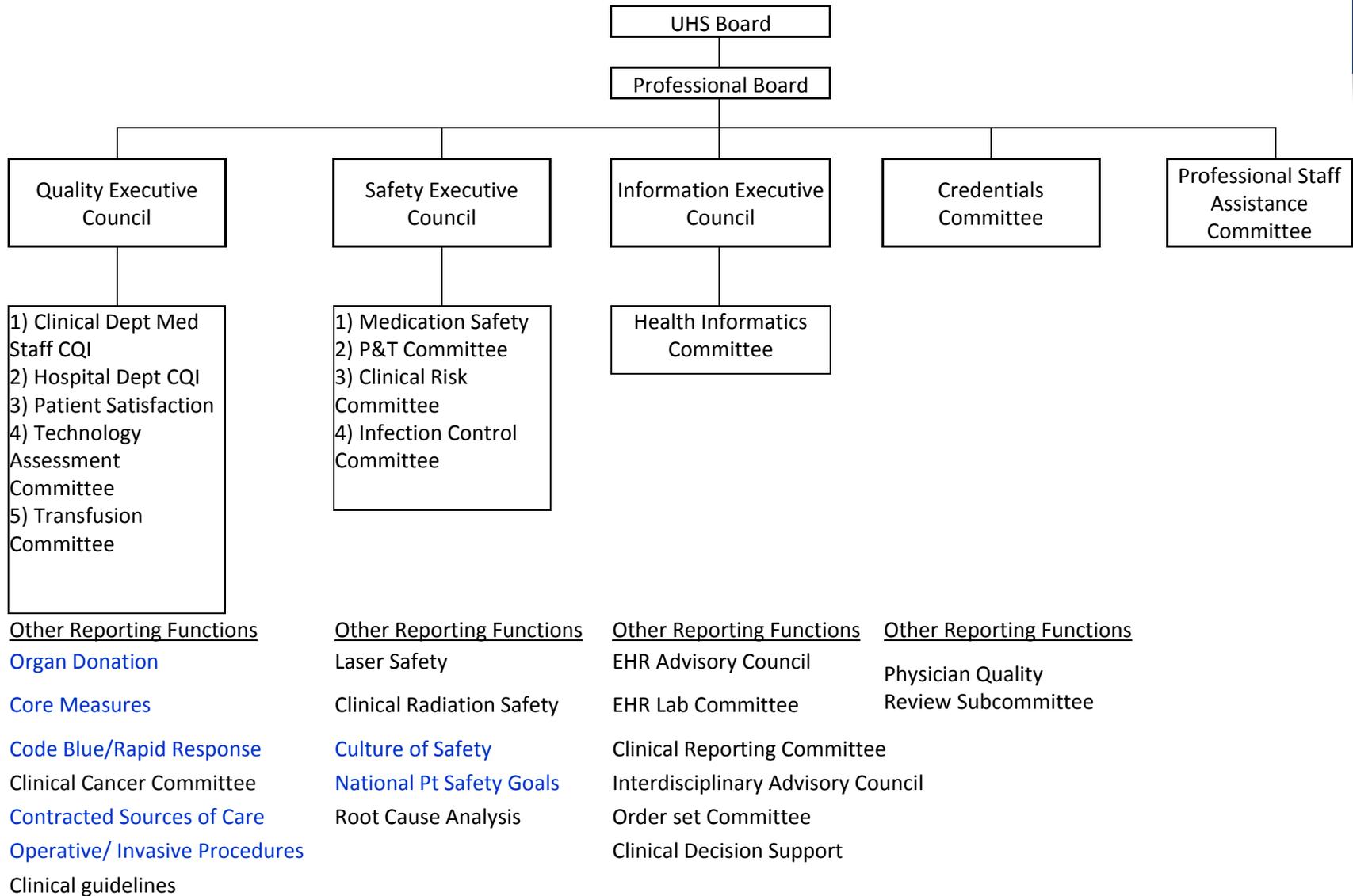
— = quality accountability  
— = employment/operational performance accountability

## OHSU Professional Staff Committee Structure, March 2012

Document in Bylaws

Org/Functions Manual

Functions within Council Charter



NOTES: Only the committees directly linked to the organizational chart are would be documented as "formal committees" of the medical staff within the Bylaws supporting document (Organization and Functions Manual). Committees and reporting topics that are being recommended to become hospital-based, and therefore reporting either through Hospital Administration or the Continuous Compliance Committee, are not reflected on this document. Blue items represent topics that are identified as necessary by The Joint Commission.

# OHSU Facilities Master Plan: Nine Themes to Guide Campus Development and Growth



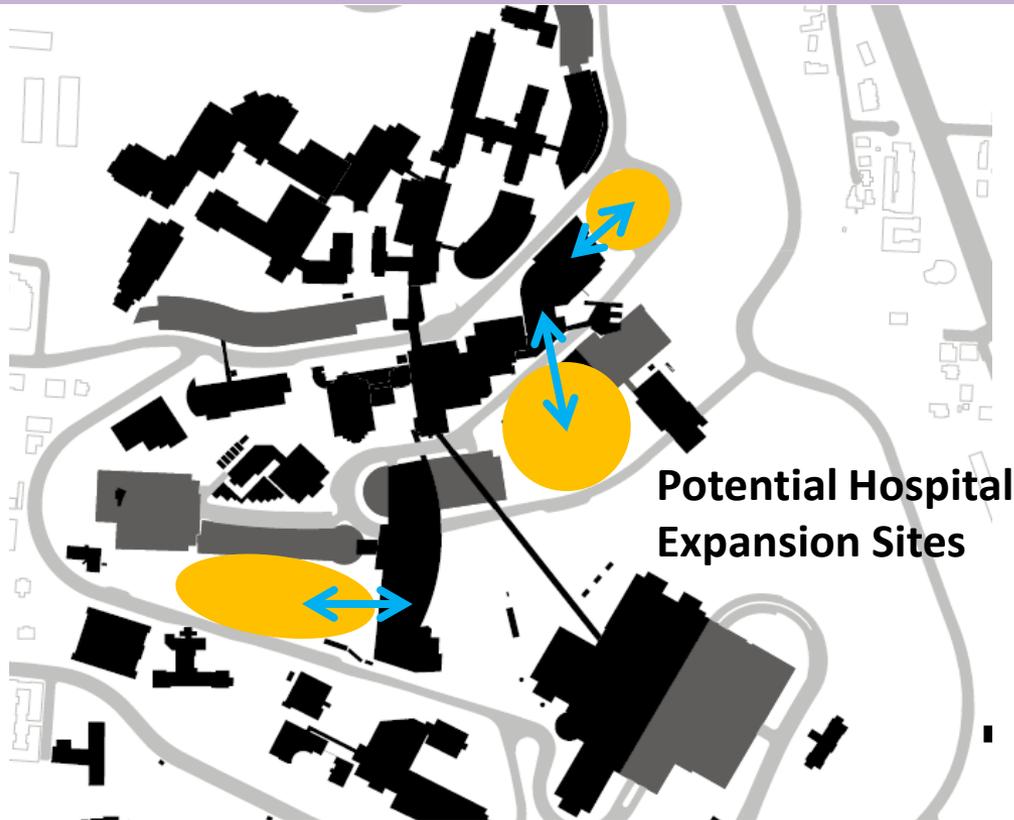
Brian Newman,  
OHSU Campus Planning,  
Development & Real Estate

## About the Plan:

- The Facilities Master Plan is intended to be a flexible framework to guide growth and development of OHSU's multiple campuses and facilities.
- Each project will require its own due diligence and financial analysis before being approved by the ELT and OHSU Board.
- Some projects will be implemented as proposed, but most will evolve due to market and technological changes. Undoubtedly, some projects will not proceed.
- Campus Planning and Development will amend the plan every two years and undertake a significant update every ten years.

# FACILITIES MASTER PLAN THEMES

1. Preserve remaining development capacity on Marquam Hill for hospital expansion, including the School of Dentistry site.



2. Implement the Schnitzer Campus Master Plan and relocate all academic schools and programs to the new campus over the next 25 years.



# PHASE ONE OF THE SCHNITZER CAMPUS: CLSB



3. Preserve land in South Waterfront near the Center for Health and Healing and the Tram for outpatient expansion and to centralize OHSU support services in one location.



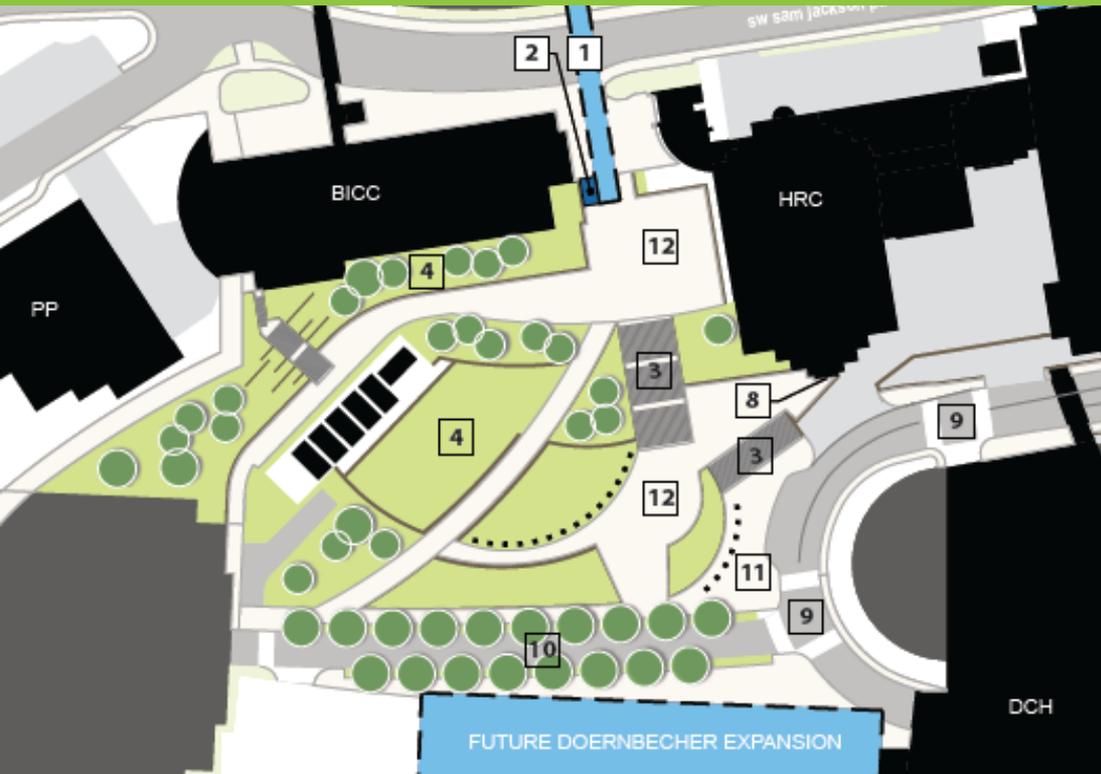
- 4. Focus research activities on three campuses: Marquam Hill, Schnitzer and the West Campus. Limit future research growth elsewhere due to the cost of research support and core facilities.**



5. Link facility expansion directly with building demolition and backfill in order to address significant deferred maintenance costs and to integrate open space.



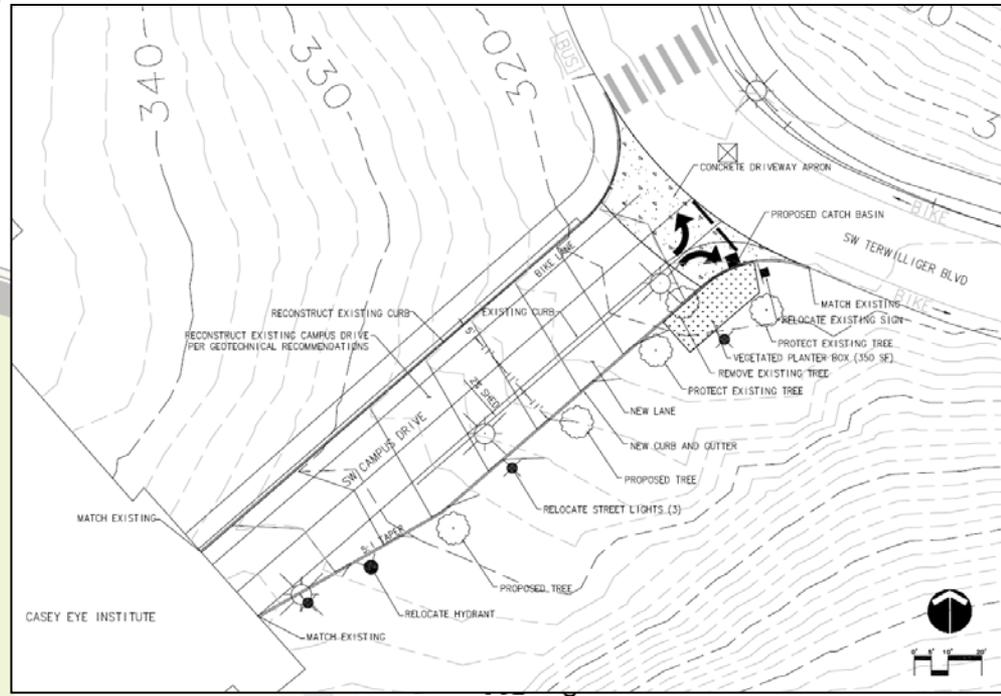
6. Seek opportunities for “campus repair” on Marquam Hill by developing complimentary relationships between buildings, landscaped areas and plazas.



## 7. Enhance the intersection of Campus Drive and Terwilliger Blvd. to become the official public entrance to the Marquam Hill Campus.



- Monument Signage, New Lighting;
- Landscape Improvements;
- Right-Hand Turn Lane;
- Trail Connection to Sam Jackson Park Rd.



## 8. Continue efforts to connect OHSU campuses and facilities to regional high capacity transit network.

### New Transit Bridge



Streetcar



Aerial  
Tram



MAX Light Rail

9. Achieve a high level of environmental sustainability with all campus development and facility projects.



# POTENTIAL OHSU CAMPUS & FACILITY GROWTH



**SCHNITZER CAMPUS**

**SOUTH WATERFRONT CENTRAL DISTRICT**

Potential OHSU facility  
and campus development  
in 2030

**MARQUAM HILL CAMPUS**

# For more information on the OHSU Facilities Master Plan:

[www.ohsu.edu/cpdre](http://www.ohsu.edu/cpdre)

503-346-0005

[newmanb@ohsu.edu](mailto:newmanb@ohsu.edu)



Brian Newman,  
OHSU Campus Planning,  
Development & Real Estate



# Research Roadmap School of Medicine

# The Need for Strategic Planning

**“The external landscape facing academic medicine is changing rapidly, including evolving scientific and public policy priorities for research funding.**

**Within this context, medical schools have new opportunities and new challenges associated with continuing to best meet our social responsibility to improve human health and well-being.”**

# A call for planning in the School of Medicine.....

**Fall, 2010**

**Mark Richardson and Dan Dorsa requested the development of a strategic plan for research to guide investment and resource allocation.**

**Mark Richardson issued a charge to faculty to tap their insights, knowledge and innovation to develop a balanced and long-term strategy to continue to advance science and research at OHSU in the context of the evolving environment.”**

# WHY NOW?

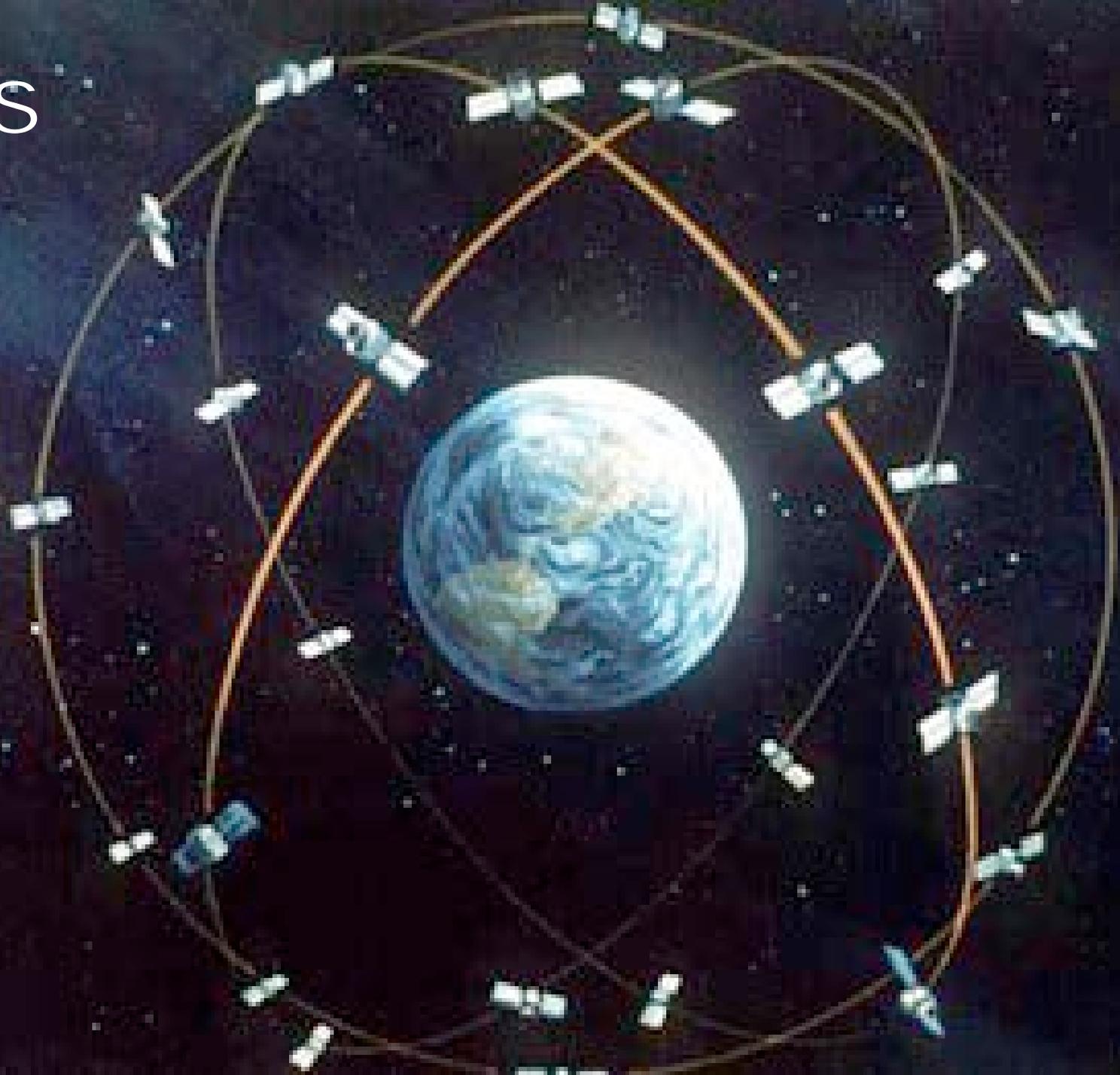
## Critical intersection of challenges:

- We have become dependent on advanced technologies.
- NIH funding has dropped and will remain low for the near future.
- The need to partner with industry is essential for innovation.
- There is an urgent need to translate discoveries into applications.

***To meet these challenges the need for careful planning is greater than ever.***



GPS



# Research Roadmap “Architects”: 100 faculty

[www.ohsu.edu/researchroadmap](http://www.ohsu.edu/researchroadmap)

**Faculty perspective on our collective future and includes ways to foster discovery and organize and administer research strategically within the School of Medicine**

Nabil Alkayed  
Joan Ash  
Abhijit Banerjee  
Irene Barhyte  
Bridget Barnes  
Thomas Becker  
Tom Beer  
Dennis Bourdette  
Lynne Boyle  
Aaron Caughey  
Michael Chapman  
Gary Chiodo  
Christopher Corless  
Lisa Coussens  
John Crabbe  
Jennifer Crosby  
Michael Davey  
David Dawson  
David Dilts  
Dana Director  
Daniel Dorsa  
Rachel Dresbeck  
Brian Druker  
Robert Duvoisin  
Julie Earnest  
Patrice Eiff  
David Ellison  
Jamie Fitzgerald

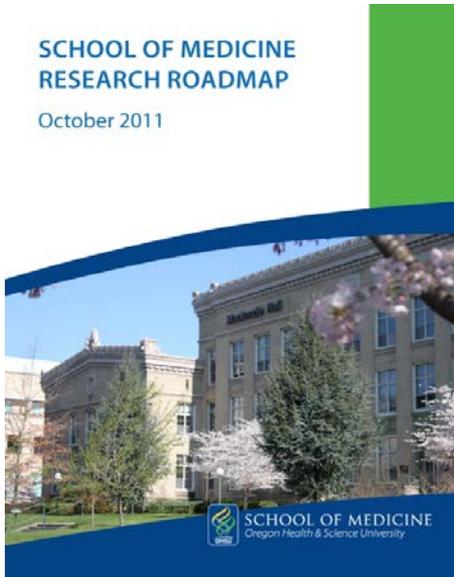
Paul Flint  
Melanie Fried-Oken  
Klaus Früh  
Allison Fryer  
Joe Gray  
Jeanne-Marie Guise  
Melissa Haendel  
Nancy Haigwood  
Cary Harding  
Susan Hayflick  
Bobby Heagerty  
Michael Heinrich  
Mary Heinricher  
Bill Hersh  
Robert Hitzemann  
Maureen Hoatlin  
Amanda Horton  
John Hunter  
David Jacoby  
Jeffrey Jensen  
Leslie Kahl  
George Keepers  
Frederick Keller  
Chuck Kilo  
David Koeller  
Charlotte Kubicky  
Molly Kulesz-Martin  
Scott Landfear

Stephen Lloyd  
Bob Lowe  
Michael MacRae  
Daniel Marks  
Cheryl Maslen  
Richard Maurer  
Dennis McCarty  
Owen McCarty  
John McConnell  
Kathleen McFall  
Cynthia Morris  
David Morton  
Jay Nelson  
Craig Newgard  
Stacy Nicholson  
John Nutt  
Alfred Nuttall  
Susan Olson  
Eric Orwoll  
Tamara Phillips  
SuEllen Pommier  
Joseph Quinn  
Mark Richardson  
Charles Roberts  
Bill Rooney  
Peter Rotwein  
Elaine Rowzee  
Mary Samuels

Kathryn Schuff  
Rosalie Sears  
Show-Ling Shyng  
Tom Soderling  
Robert Steiner  
Mary Stenzel-Poore  
Tim Stout  
Lori Sweeney  
Charles Thomas  
Kent Thornburg  
Buddy Ullman  
Tania Vu  
Douglas Weeks  
David Wilson  
Bruce Wolfe  
Brian Wong

SCHOOL OF MEDICINE  
RESEARCH ROADMAP

October 2011



# SoM Research Roadmap Vision

**By 2016, the OHSU School of Medicine will be recognized globally for excellence in scientific discovery, collaboration, and the rapid translation of new knowledge into practices that improve human health.**

***To achieve this vision we will:***

- **Nurture, support and invest in a scientific culture that rewards innovation and collaboration.**
- **Strengthen our research training infrastructure, and create new education models and curricula that advance our scientific excellence.**
- **Develop strategic external interactions and partnerships.**
- **Increase awareness, understanding and support for OHSU biomedical research.**

# Roadmap Framework: Six Strategic Initiatives

## ***Strategic Initiative #1***

Identify and invest in areas of research strength that make best use of OHSU SoM resources to advance human health and well-being.

## ***Strategic Initiative #2***

Advance OHSU capacity in translational research.

## ***Strategic Initiative #3***

Ensure research excellence through effective organizational systems and infrastructure.

## ***Strategic Initiative #4***

Enhance research training, research career development and research mentoring opportunities for the next generation of biomedical investigators.

## ***Strategic Initiative #5***

Promote, nurture and support a professionally rewarding culture for researchers at OHSU.

## ***Strategic Initiative #6***

Increase awareness, appreciation, and understanding of the value of research at OHSU to both internal and external stakeholders and the public.

# RESEARCH ROADMAP PROCESS

**The Research Roadmap planning process includes the practical implementation of strategies and tactics for each strategic initiative.**

- **Implementation plans will be reviewed annually, integrated across the Roadmap and updated and evaluated for outcome progress.**
- **Developed by faculty and staff with input from content experts.**
- **Evaluated annually to determine resource needs and integrated with ongoing OHSU-wide initiatives.**
- **Staged implementation according to SoM strategic priorities and resource needs.**

# RESEARCH ROADMAP PROCESS

## IMPLEMENTATION ORGANIZATION

- **6 Blueprint task forces, one for each strategic initiative.**
- **Blueprint Leadership: Chair is a faculty member; co-chair has an institutional role for additional help and guidance of the process.**
- **Blueprint task forces will be comprised of faculty and staff; each term will be 2 years for faculty.**
- **Implementation plans for each strategic initiative will be developed by the Blueprint task force.**
- **Regular updates to the Collaborative Research Leadership group.**
- **Annual review and resource allocation plan.**

# COUNCIL FOR RESEARCH OPPORTUNITIES AND STRENGTHS

## **CROS Charge**

Develop and apply principles for resource allocation to and investment in distinctive and emergent research areas.

## **CROS Composition**

Leaders and faculty representing the breadth of the School of Medicine's research mission.

## **CROS Membership**

Determined via a mix of permanent positions, appointments by the Dean of the School of Medicine and 5 positions elected by faculty in the School of Medicine. Elected terms are limited to two years. Chairperson to be appointed by the Dean.

# COUNCIL FOR RESEARCH OPPORTUNITIES AND STRENGTHS

- **MARY STENZEL-POORE, Associate Dean for Basic Science**
- **ERIC ORWOLL, Associate Dean for Clinical Science**
- **DAVID ELLISON, Chair of Research Committee**
- **SUSAN HAYFLICK, Basic Science Chair**
- **BILL HERSH, Clinical Chair**
- **TIM STOUT, Director, TTBD**
- **DAN DORSA, Vice President for Research**
- **CHUCK KILO, Chief Medical Officer**
- **CONSTANCE FRENCH, OHSUF**
  
- **Translational Researcher (nominated by CRLG; elected by SoM faculty)**
- **Basic Researcher (nominated by the CRLG; elected by SoM faculty)**
- **Clinical Researcher (nominated by CRLG; elected by SoM faculty)**
- **Member at Large (appointed by the Dean)**

# EMERGING ACCOMPLISHMENTS

- **Actively prioritizing and identifying responsible parties for initiatives.**
- **Identifying critical gaps in expertise that reduce capacity for research excellence (e.g. computational biology, statistical genetics)**
- **Developing data-driven criteria to identify emerging strengths that “lead in the creation and rapid application of scientific knowledge to health care,” as well as emerging priorities of NIH (e.g. SciVal)**
- **Proposal for a new program in Quantitative Biosciences that includes training and faculty development in Systems and Computational Biology.**

# IMMEDIATE OUTCOMES

- **Promotion and Tenure guidelines modified to recognize “team” contributions and outstanding team support by faculty.**
- **Review of training programs for biomedical research and recommendations for future organization and curriculum development (task force recommendations).**
- **Specific recommendations for improving research faculty recognition, making better use of current channels for recognition .**
- **Increased focus on research faculty participation and collaboration with the expanding “Research Week” event in May 2012.**
- **NIH Directors will visit OHSU in Spring and Fall 2012 to increase OHSU visibility at NIH.**

# RESEARCH ROADMAP

- **Part of a long-term strategy to successfully meet our greatest challenges.**
- **Process designed to allow “course corrections” in response to new data, changing funding, emerging opportunities and partnerships.**
- **Involvement of research leadership in planning process builds new collaboration potential within OHSU and a greater understanding of the overall research map.**
- **Increases our understanding of how current resources can be put to use to improve research effectiveness.**
- **Planning process allows us to make strategic decisions on how to raise the profile of OHSU research regionally, nationally and globally.**

# SCHOOL OF MEDICINE RESEARCH ROADMAP

October 2011



SCHOOL OF MEDICINE  
*Oregon Health & Science University*



## RESEARCH VISION

By 2016, the OHSU School of Medicine will be recognized globally for excellence in scientific discovery, collaboration and the rapid translation of new knowledge into practices that improve human health.

*To achieve this vision we will:*

- Nurture, support and invest in a scientific culture that rewards innovation and collaboration.
- Strengthen our research training infrastructure and create new education models and curricula that advance our scientific excellence.
- Develop strategic external interactions and partnerships.
- Increase awareness, understanding and support for OHSU biomedical research.

## STRATEGIC INITIATIVES

1. Identify and invest in areas of research strength that make best use of School of Medicine resources to advance human health and well-being.
2. Advance School of Medicine capacity in translational research.
3. Promote research excellence through effective organizational systems and infrastructure.
4. Enhance training, career development and mentoring opportunities for the next generation of biomedical researchers.
5. Promote, nurture and support a professionally rewarding culture for researchers at OHSU.
6. Increase awareness, appreciation and understanding of the value of research at OHSU to both internal and external stakeholders and the public.

## MESSAGE FROM DEAN RICHARDSON



Dear Colleagues,

The external landscape facing academic medicine is changing rapidly, including evolving scientific and public policy priorities for research funding. Within this context, medical schools have new opportunities and new challenges associated with continuing to best meet our social responsibility to improve human health and well-being.

At the Research Roadmap Retreat in December 2010, I issued a charge to faculty to tap their insights, knowledge and innovation to develop a balanced and long-term strategy to continue to advance science and research at OHSU in the context of the evolving environment.

This Research Roadmap admirably meets this charge. It is a thoughtful and timely plan. I endorse this Research Roadmap and the six Strategic Initiatives it contains. Now, as we move into an implementation phase, we must continue to work together and hold ourselves mutually responsible for and accountable to these goals.

Some of the recommendations have already gained traction and are getting underway. Detailed implementation plans will be developed and initiated continuously over the next several years, and will include methods to measure success and progress.

The faculty-driven collaborative framework established by this planning process is a model for how we can work together to identify the best ways to meet our collective goals for excellence and maximum impact in our research mission.

I appreciate the hard work of everyone involved in this planning process and am grateful for your commitment to the School of Medicine and our missions.

Mark Richardson, M.D., M.Sc.B., M.B.A.  
Dean, School of Medicine

# PLANNING LEADERSHIP

The School of Medicine Research Roadmap is the result of a collaborative planning process that included all departments, centers and institutes in the School of Medicine and represented the input of our faculty. Six task force committees, led by twelve co-chairs, were charged with identifying consensus objectives and outcomes to support the realization of the six Strategic Initiatives that form the basis of the Research Roadmap. The resulting recommendations for the six Strategic Initiatives reflect the thoughtful work of the task force members in collaboration with Dean Richardson.

As co-chairs of the OHSU School of Medicine Research Roadmap task force committees, we acknowledge the importance of creating a participatory and ongoing process to achieve “excellence in scientific discovery, collaboration, and the rapid translation of new knowledge into practices that improve human health.” We, together with the Associate Deans for Basic Science and Clinical Research, support and endorse the recommendations herein.



David C. Dawson, Ph.D.  
Professor and Chair  
Department of Physiology & Pharmacology, OHSU



George Keepers, M.D., DFAPA  
Carruthers Professor and Chair  
Department of Psychiatry, OHSU



David H. Ellison, M.D., FASN, FAHA  
Head, Division of Nephrology & Hypertension  
Professor, Departments of Medicine and Physiology & Pharmacology, OHSU  
Staff Physician, Portland VA Medical Center



Charles M. Kilo, M.D., MPH  
Chief Medical Officer  
OHSU Healthcare



Paul W. Flint, M.D.  
Professor and Chair  
Department of Otolaryngology/Head & Neck Surgery, OHSU



H. Stacy Nicholson, M.D.  
Credit Union for Kids Professor and Chair  
Department of Pediatrics, OHSU



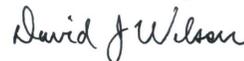
Nancy L. Haigwood, Ph.D.  
Director, Oregon National Primate Research Center  
Senior Scientist, Division of Pathobiology and Immunology, Vaccine & Gene Therapy Institute  
Adjunct Professor, Department of Molecular Microbiology & Immunology, OHSU



Rosalie C. Sears, Ph.D.  
Associate Professor  
Department of Molecular & Medical Genetics, OHSU  
Leader, Cancer Biology Program, Knight Cancer Institute



Susan J. Hayflick, M.D.  
Professor and Chair  
Department of Molecular & Medical Genetics  
Professor, Departments of Pediatrics & Neurology, OHSU



David J. Wilson, M.D.  
Thiele Petti Professor and Chair  
Department of Ophthalmology, OHSU  
Director, Casey Eye Institute



Robert J. Hitzemann, Ph.D.  
Professor and Chair  
Department of Behavioral Neuroscience, OHSU



Eric Orwoll, M.D.  
Professor, Department of Medicine, OHSU  
Director, Oregon Clinical and Translational Research Institute  
Associate Dean, Clinical Research, SoM  
Associate Vice President for Research



Maureen Hoatlin, Ph.D., M.B.A.  
Associate Professor  
Departments of Biochemistry & Molecular Biology and Molecular & Medical Genetics, OHSU  
Member, Hematologic Malignancies Program, OHSU Knight Cancer Institute  
Co-Chair, OHSU Rare Disorders Research Consortium



Mary Stenzel-Poore, Ph.D.  
Professor and Chair  
Department of Molecular Microbiology & Immunology, OHSU  
Associate Dean, Basic Science, SoM



## RESEARCH ROADMAP

Over the past two decades, OHSU has experienced tremendous growth in research. In 1990, total grant awards to OHSU were \$43 million. In 2011, this figure had grown to about \$325 million. In parallel, OHSU experienced a rapid growth in research programs, initiatives and discoveries, along with an increase in faculty, staff and graduate studies programs. Much of this growth occurred in the School of Medicine. Today, the School of Medicine departments, centers and institutes collectively receive nearly two-thirds of all grants awarded to OHSU.

The School of Medicine Research Roadmap is intended to guide the future scientific focus and strategic direction of our research mission. The Research Roadmap identifies and takes into consideration internal opportunities as well as external factors that influence research activities and funding in the United States, now and likely for the foreseeable future.

There is a compelling need to translate the rapid explosion of basic science discoveries into therapeutic treatments and cures for a wide range of diseases. Growing efforts to improve health care quality and reduce costs provide critical emphasis on comparative effectiveness research, population studies and related topics. Further, future scientific and funding challenges, as well as opportunities, require new models for collaboration and investment to ensure strong technological, intellectual and educational foundations essential to continue to nurture innovation and discovery.

The Research Roadmap captures faculty perspectives on our collective future, and includes ways to foster discovery and organize and administer research strategically within the School of Medicine. The Research Roadmap is comprised of six Strategic Initiatives and related recommendations that, taken together, will enhance and sustain a vibrant, collegial and collaborative professional research environment dedicated to excellence.

The Research Roadmap is the result of a planning process launched in the fall of 2010, which engaged research faculty, leadership and administration in discussions about strategies that would support best use of resources and opportunities to impact human health. This process was led by the OHSU Collaborative Research Leadership Group (CRLG). Comprised of research leadership across OHSU, the CRLG was formed in 2009 to share information about different areas of growth and development and emphasis in the research mission.

A Research Roadmap retreat, held December 1 and 2, 2010, initiated the planning process with more than 60 retreat participants representing a broad range of research areas and viewpoints. The goal was to explore and develop a strategic path toward increased research success and impact over the next decade.

The group identified regional, national and global research trends and needs, and also considered the future direction of federal and other funding sources. The group reviewed the current state of research and its administration at OHSU, as well as our readiness to engage proactively with the evolving external landscape to leverage the resources of our strong, nationally prominent research mission.

The group developed six over-arching Strategic Initiatives, which collectively provided the framework for the development of specific research goals and recommendations for the School of Medicine. A subsequent year-long process, which included input from six faculty task forces and an all-faculty survey, resulted in the refinement of the goals and outcomes associated with the six Strategic Initiatives. During this process, a Research Vision statement was also developed.

The six Strategic Initiatives are:

*Identify and invest in areas of research strength that make best use of School of Medicine resources to advance human health and well-being.*

*Advance School of Medicine capacity in translational research.*

*Promote research excellence through effective organizational systems and infrastructure.*

*Enhance training, career development and mentoring opportunities for the next generation of biomedical researchers.*

*Promote, nurture and support a professionally rewarding culture for researchers at OHSU.*

*Increase awareness, appreciation and understanding of the value of research at OHSU to both internal and external stakeholders and the public.*

The Research Roadmap initiatives apply to the departments, centers, institutes and other units within the School of Medicine. Given that an overarching School of Medicine goal is to support collaboration at all levels and across all missions, the planning process itself was highly inclusive. Many of the resulting recommendations included in the Research Roadmap are intended to benefit the broader OHSU research community and mission.

With the completion of the Research Roadmap, the planning process has now entered a new phase focused on implementation, referred to as the “blueprint.” This approach will involve an annual process to develop implementation plans, funding strategies and an accountability framework for each Strategic Initiative. Faculty members and research staff will continue to inform the blueprint phase, using the Research Roadmap as a guide as to achieve specific goals for the next five years.

# STRATEGIC INITIATIVES

## GUIDING FRAMEWORK

Outlined in this section of the Research Roadmap are the six Strategic Initiatives that are aimed specifically at the actualization of the School of Medicine's Research Vision.



Development of these is the outcome of numerous facilitated input activities and group deliberations, including an initial Research Roadmap planning retreat, a faculty survey, steering committee and task force deliberations, and regular reviews by the Collaborative Research Leadership Group. Further information on the planning process and methods is contained in a separate Research Roadmap Appendix.

Collectively, the strategic initiatives provide a guiding framework for the School of Medicine to address future decisions and investments in research over the next five years. For each strategic initiative a “blueprint” will be developed to outline a specific plan for addressing the strategic initiative, including ongoing strategies and tactics grounded by measurable outcomes. This first blueprint will cover the first 18 months, and will continue to be guided and informed by the participation of the Strategic Initiative task forces, the Collaborative Research Leadership Group and others with special expertise in various aspects of research support and development.

***Identify and invest in areas of research strength that make best use of School of Medicine resources to advance human health and well-being.***

Investigations into the complex scientific questions of our era depend on developing new areas of expertise, and on supporting collaborative and multi-disciplinary models of inquiry. In parallel, novel funding sources and partnerships need to be identified and cultivated to realize and sustain research success in an era in which traditional funding sources are expected to shift and/or be constrained. The continued success of the School of Medicine is linked to the development of systems that support the strategic and collaborative allocation of School of Medicine resources in ways that maximize our collective impact on human health, while enhancing the vibrant intellectual and technological foundation essential to ensure future discovery.

Strategic Initiative #1 will create a framework that is objective, facile and driven by metrics to facilitate strategic allocation of School of Medicine resources. As part of this initiative, we will undertake the development and transparent application of data, methods and systems to define and identify distinctive and emergent research areas within the School of Medicine. A key aspect of Strategic Initiative #1 is the establishment of the School of Medicine Council for Research Opportunities and Strategies (CROS). CROS will develop and apply principles for resource allocation to and investment in distinctive and emergent research areas.

CROS will be comprised of leaders and faculty who represent the breadth of the School of Medicine's research mission, and will include representatives that can help drive collaboration across all missions. CROS membership will be determined via a mix of permanent positions, appointments by the Dean of the School of Medicine and positions elected by a vote of the School of Medicine faculty.

# STRATEGIC INITIATIVE #1

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## STRATEGIES

- 1. Identify areas of emergent and distinctive research.**
  - a. Develop an ongoing data-driven process to define distinctive and emergent areas of research in the School of Medicine.
  - b. Establish a Council for Research Opportunities and Strategies (CROS) to evaluate and prioritize research initiatives for resource allocation.
  - c. Create multidisciplinary interest groups aligned with each distinctive research theme or area of emergent opportunity.
- 2. Support areas of emergent and distinctive research.**
  - a. Expand the capacity for seed funding.
  - b. Bolster School of Medicine and OHSU Foundation strategies to cultivate interest by local foundations in the Research Roadmap strategic priorities.
  - c. Evaluate organization and principles of the School of Medicine Research Committee to strengthen membership and ensure fulfillment of strategic research priorities.
  - d. Conduct a needs assessment related to institutional support for grant applications and implement recommendations.
  - e. Create a strategic plan for computational biology that incorporates current and future needs for research.
- 3. Enhance School of Medicine infrastructure to directly support faculty success for funding beyond current levels from all relevant funding sources.**
  - a. Promote existing resources to identify collaborators and form partnerships.
  - b. Perform a needs assessment of resources for automated, targeted funding searches and increase such resources if needed.
- 4. Develop strategic research collaborations between OHSU and industry partners.**

***Advance the School of Medicine capacity in translational research.***

We are in an exceptionally prolific and historic period of discovery with new knowledge emerging from the full spectrum of research including basic and translational sciences, technology development and systematic comparative evidence-based analyses. The promise of genetics and molecularly-targeted medicine, as well as the potential to apply evidence to transform clinical practice, among other opportunities, has never been greater. Such promise, however, requires emphasizing, developing and sustaining the specific multi-disciplinary faculty expertise and institutional capacity needed to rapidly apply science and new knowledge into clinical practice, as well as to provide relevant information back to researchers from the clinical realm in ways that direct future initiatives.

Strategic Initiative #2 will expand and accelerate our capacity in translational research and allow us to become global leaders in the rapid application of science and knowledge to improve human health and well-being. The primary strategies will support and invest in faculty expertise, programs, technology, partnerships and educational models to enable translational success. Implementation of this initiative will simultaneously identify and remove existing institutional barriers to translational success, and foster innovative partnerships with clinical entities and industry.

# STRATEGIC INITIATIVE #2

## STRATEGIES

- 1. Identify and optimize new funding streams (e.g., pharma, non-NIH government, insurance, DOD, foundations) to advance translational capacity.**
  - a. Evaluate current OHSU resources in context with known NIH translational pipelines.
  - b. Explore new funding streams, and potential partners (NIH, DOD, insurance companies, pharmaceutical companies, other academic institutions) for investment in OHSU's focus areas in translational research.
- 2. Foster faculty engagement and facilitate proficiency in translational research.**
  - a. Mentor faculty in translational research.
  - b. Evaluate current educational programs with a focus on translational medicine and identify areas for improvement or expansion.
  - c. Define and strengthen criteria in promotion and tenure considerations that recognize and value efforts by faculty to advance collaborative translational research and team science.
  - d. Increase awareness of the nature and breadth of translational research.
- 3. Increase awareness among faculty and potential external collaborators of resources available to support translational research.**
  - a. Identify gaps and barriers for translational research across the entire translational spectrum.
  - b. Promote and emphasize maximum utilization of Oregon Clinical & Translational Institute (OCTRI) resources to support translational research.
- 4. Enhance collaboration with partners across the translational spectrum.**
  - a. Explore and select a new operational model for efficient interactions among translational stakeholders, including pharmaceutical and insurance companies, and government agencies such as DARPA, AMCs, etc.
  - b. Align School of Medicine institutional and individual (Principal Investigator) financial incentives for translational research success.
  - c. Evaluate institutional barriers that may impede collaborations with external partners.

***Promote research excellence through effective organizational systems and infrastructure.***

Administrative, management and research support systems have the potential to better facilitate the success of researchers with the strategic application of advanced information technology and tools. Similarly, regulatory requirements, which continue to grow, can be managed more effectively on behalf of investigators with coordinated planning, cultivation of staff expertise, and strategic deployment of appropriate database and tracking tools. To help realize the vision and goals of the Research Roadmap, we will centralize and leverage the power of information technology and expertise to improve overall efficiency and impact in ways that support faculty productivity and innovation at all levels of our research mission.

Strategic Initiative #3 will define, implement and continuously improve the organizational, administrative and technical infrastructure and systems that enable success across the spectrum of research administration—from idea conception to grant submission to experimental design and execution to technology transfer, and beyond.

## STRATEGIC INITIATIVE #3

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### STRATEGIES

- 1. Develop and fund a dedicated process improvement program to facilitate research applications.**
  - a. Utilize the process improvement program to identify the key infrastructure and system requirements that are necessary to successfully execute applications.
  - b. Coordinate and implement process improvement efforts in the School of Medicine with similar efforts underway across OHSU.
- 2. Define, review and implement balanced standards in all areas of research regulatory compliance.**
  - a. Ensure faculty input in the design and implementation of compliance requirements and policy consistent with methods established by existing oversight boards.
- 3. Continually evaluate and invest in centralized information technology and related tools that function seamlessly and efficiently across all units.**
  - a. Identify the unmet needs for information technology in OHSU's research community.
  - b. Develop institutional plans for biostatistical resource and bioinformatics support.
- 4. Identify and address barriers to research collaborations between the School of Medicine and the Portland Veterans Affairs Medical Center.**
  - a. Utilize the existing Portland Veterans Affairs Medical Center (PVAMC) and School of Medicine oversight committee to identify barriers to research collaborations.

***Enhance training, career development and mentoring opportunities for the next generation of biomedical researchers.***

The sustained excellence of biomedical research and the continued collective ability of our research community to improve human health depend on the quality of our educational programs and mentoring capacity. There is a pressing call for curriculum transformation to integrate education across disciplines in creative ways that meet the needs of basic, translational and clinical research.

Strategic Initiative #4 will enhance and sustain an educational platform and curricula that will attract, train and retain outstanding graduate students, post doctoral fellows and early career development faculty. This initiative will also ensure that our educational models and curricula align with our goals for excellence and diversity.

# STRATEGIC INITIATIVE #4

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## STRATEGIES

- 1. Attract and support graduate trainees consistent with the Research Roadmap vision for excellence and diversity.**
  - a. Define attributes and specify academic qualifications of next-generation trainees that would fulfill the vision of the Research Roadmap.
  - b. Identify new sources of internal and external funding for graduate students and postdoctoral fellows.
  - c. Develop a school-wide strategic plan for recruitment of under-represented minority students.
  
- 2. Oversee the graduate studies education mission in the Office of the Dean to ensure an organizational structure that supports uniform quality/consistency in a comprehensive framework and conserves resources.**
  - a. Develop appropriate dedicated leadership and staff support for the Graduate Studies Office.
  
- 3. Enhance graduate and postgraduate training and career development to support excellence and state-of-the-art training in the research mission.**
  - a. Develop an institutional plan to meet educational and career development needs of all research trainees.
  - b. Emphasize curriculum content in ethics, translation, scientific education and entrepreneurial focus.
  - c. Capitalize on existing Clinical Scientist K Program and OCTRI resources and expertise to develop internal standards for the management of K-Awards across OHSU units. Where possible, utilize existing OCTRI standards and practices to guide management of K-awards.

***Promote, nurture and support a professionally rewarding culture for researchers at OHSU.***

Research excellence and productivity are fundamentally linked to professional satisfaction, meaningful opportunities for success, recognition of achievement and attainment of individual work-life balance. This professional culture will help ensure that we consistently recruit, retain and reward a highly productive, collaborative and innovative faculty.

Strategic Initiative #5 will enhance and expand our professional culture to reward and recognize researchers for their achievements while providing an environment that facilitates the connectivity essential for innovation, collaboration and success. This initiative emphasizes the inherent and essential value in supporting and rewarding a culture that performs research, teaches and mentors, all within the context of well-balanced work-life expectations.

## STRATEGIC INITIATIVE #5

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### STRATEGIES

- 1. Reward scientific achievement, collaborative research accomplishment, and research mentoring and teaching.**
  - a. Create a program that promotes, recognizes and rewards excellence in scientific achievement, collaboration, mentorship and teaching.
- 2. Promote strong, supportive, and effective research leadership through all organizational levels of the School of Medicine.**
  - a. Implement a systematic approach to research leadership development using both internal and external capabilities.
  - b. Evaluate School of Medicine leadership for effectiveness in advancing the research mission.
- 3. Create and implement a formal mentoring program for research faculty.**
- 4. Advocate for stronger OHSU programs that support and deliver professional development to both faculty and staff who are vital to the success of the research mission.**
  - a. Work with OHSU leadership to find resources that support work-life balance.
  - b. Ensure that faculty, staff and students have access to and utilize preventive health, primary care, mental health care and specialty health services when needed.
- 5. Improve opportunities for socialization and connection within and across departments and institutes.**
  - a. Provide avenues for increased connectivity, collaboration and collegiality among all research personnel.

***Increase awareness, appreciation and understanding of the value of research at OHSU to both internal and external stakeholders and the public.***

Effective communication of our research excellence and breadth will increase local, national and global recognition. Enhanced recognition will help sustain and advance our scientific and funding goals. In parallel, increasing internal awareness of distinctive and emergent research areas, research initiatives, expertise and priorities between departments and among the faculty as well as our research leaders, will help meet our goals for discovery, innovation and collaboration.

Strategic Initiative #6 will create and execute a coordinated research communications plan that places specific emphasis on the areas, goals and initiatives of the Research Roadmap. This initiative identifies critical functions for faculty in the ongoing dissemination of relevant information about the importance of research to key audiences. An outcome of Strategic Initiative #6 will be the establishment of the Research Communications Committee (RCC) to direct and advise on all aspects of research communications in the School of Medicine. The RCC will be comprised of research leaders and faculty, working together with OHSU communications, community relations and other experts across OHSU.

## STRATEGIC INITIATIVE #6

### STRATEGIES

- 1. Create and charge a Research Communications Committee (RCC) comprised of communicators and faculty to direct/advise on research communications and serve in a permanent advisory capacity for School of Medicine research communications.**
- 2. Enhance internal understanding of and appreciation for the depth and breadth of research within the School of Medicine.**
  - a. Support internal communications tools that describe the landscape of research and provide regular updates about research for investigators, administrators and leadership.
- 3. Actively partner with the OHSU Foundation to communicate research priorities and funding opportunities.**
  - a. Educate faculty and communications constituents about the OHSU Foundation's current fundraising focus and develop tactics for additional partnering.
  - b. Demonstrate impact of philanthropy to donors through faculty accountability and transparency.
  - c. Create and continually update a research portfolio of distinctive and emergent research competencies.
- 4. Support community awareness and engagement with research.**
  - a. Promote research areas in alignment with Research Roadmap goals.
  - b. Identify and leverage existing community engagement efforts at OHSU.
  - c. Identify community and political entities and networks with which to develop ongoing relationships; seek opportunities to engage with these entities.
- 5. Provide a strategic framework to increase the national presence of OHSU research.**
  - a. Promote research nationally in alignment with the Research Roadmap goals.