Executive Summary

Fiscal Year 2011 was another exceptional year for research at Partners HealthCare. Total Research Revenue increased 12.7% from FY10 to reach an astounding $1.4B. The 2,600 distinguished Investigators within the Partners research enterprise account for nearly 13,000 active research funds that employ close to 10,000 individuals. MGH and BWH continued to lead the independent hospitals in NIH support and the Partners hospitals, collectively, were the largest recipients of NIH funding.

To fulfill RM’s primary mission of serving its Investigators, Partners Research Management (RM) is pleased to share some of its accomplishments and strategic initiatives embarked upon this past year.

FY11 was marked with a successful combination of technological innovation, process improvements, and organizational development and redesign that has proven instrumental in managing the growing research portfolio within Partners. Many of these improvements are positioning RM as a leader in the industry—setting and upholding the highest standards of integrity and stewardship, maximizing critical alliances within Partners and with area institutions and implementing best-in-class practices and trainings.

In addition to the commitment of RM leadership and staff, the improvements and strides developed and implemented throughout FY11 were also made possible by the feedback, direction and participation of the Principal Investigators (PI’s) and Department Administrators (DA’s). The following groups were instrumental in supporting RM’s efforts:

1. MGH Executive Committee on Research
2. BWH Biomedical Research Institute and the Research Oversight Committee
3. Partners Research Issues Forum
4. MGH Research Administration Advisory Committee
5. BWH BRI Research Management Task Force

Although RM’s research efforts have been successful, the research landscape is changing. Decrease in federal funding and a heightened regulatory environment has put significant burden on Investigators and the research support infrastructure requiring operational efficiency to be in the forefront as FY12 gets underway.

To assist with this focus, process maps have been developed to promote transparency and accountability across the research support groups. RM will continue to build upon such operational tools and the improvements made in FY11 to address these new challenges in the next year.
Research Activity has continued to grow substantially. Funding from the American Recovery and Reinvestment Act (ARRA) contributed to the increased activity over the past two years.

Although research revenue has continued its upward trajectory since last fiscal year, the number of proposals submitted and awards received has declined, primarily due to the ARRA funding phase out and a drop in the non-profit category. NIH awards remain flat with a 10% increase in Other Federal awards. Foundation proposals and awards grew significantly in FY11.

### Research Activity by Sponsor Type (PHS)

<table>
<thead>
<tr>
<th>Sponsor Type</th>
<th>FY10</th>
<th>FY11</th>
<th>% Change</th>
<th>FY10</th>
<th>FY11</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>2,196</td>
<td>2,039</td>
<td>-7.1%</td>
<td>631</td>
<td>632</td>
<td>0.2%</td>
</tr>
<tr>
<td>ARRA</td>
<td>48</td>
<td>21</td>
<td>-56.3%</td>
<td>156</td>
<td>50</td>
<td>-67.0%</td>
</tr>
<tr>
<td>Other Fed</td>
<td>242</td>
<td>176</td>
<td>-27.3%</td>
<td>104</td>
<td>115</td>
<td>10.6%</td>
</tr>
<tr>
<td>Industry</td>
<td>772</td>
<td>809</td>
<td>4.8%</td>
<td>436</td>
<td>400</td>
<td>-8.3%</td>
</tr>
<tr>
<td>Non Profit</td>
<td>2,538</td>
<td>1,601</td>
<td>-36.9%</td>
<td>1,245</td>
<td>928</td>
<td>-25.5%</td>
</tr>
<tr>
<td>Foundation</td>
<td>405</td>
<td>945</td>
<td>133.3%</td>
<td>173</td>
<td>302</td>
<td>74.6%</td>
</tr>
<tr>
<td>All Other</td>
<td>102</td>
<td>185</td>
<td>81.4%</td>
<td>349</td>
<td>371</td>
<td>9.1%</td>
</tr>
<tr>
<td>Total</td>
<td>6,393</td>
<td>5,776</td>
<td>-8.4%</td>
<td>3,085</td>
<td>2,798</td>
<td>-9.3%</td>
</tr>
</tbody>
</table>

### FY11 PHS Proposal Submissions

- NIH, 2,039, 35%
- ARRA, 211, 3%
- Other Fed, 176, 3%
- Industry, 809, 14%
- Non Profit, 1,601, 28%
- Foundation, 945, 16%

*Includes Research Activity and All Other Science. Does not include P&L adjustments.*
Operational Metrics

In April, RM incorporated standardized reporting into its day-to-day operational management. The snapshot below summarizes key areas across the lifecycle of an award and the progress made to achieve the targeted goal for each area. New processes and improvements have been established to effectively meet all operational goals in the upcoming fiscal year.

<table>
<thead>
<tr>
<th></th>
<th>April - October 2011</th>
<th>BWH</th>
<th>MGH</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Award Management (Programmatic and Financial)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Award Setup (completed &lt; 15 days)</td>
<td>85%</td>
<td>88%</td>
<td>532</td>
<td>89%</td>
</tr>
<tr>
<td>Renewals (completed &lt; 30 days from NOA)</td>
<td>80%</td>
<td>77%</td>
<td>845</td>
<td>75%</td>
</tr>
<tr>
<td>Accounting Journal Entries Processed (current month)</td>
<td>100%</td>
<td>97%</td>
<td>2022</td>
<td>94%</td>
</tr>
<tr>
<td>Personnel Changes Processed</td>
<td>100%</td>
<td>97%</td>
<td>4429</td>
<td>98%</td>
</tr>
<tr>
<td>Contracts</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incoming Sub, New (FEA &lt; 60 days receipt)</td>
<td>90%</td>
<td>79%</td>
<td>815</td>
<td>81%</td>
</tr>
<tr>
<td>Incoming Sub, Mod (FEA &lt; 30 days receipt)</td>
<td>90%</td>
<td>74%</td>
<td>380</td>
<td>76%</td>
</tr>
<tr>
<td>Outgoing Sub, New (PEA 30 &lt; days requested)</td>
<td>80%</td>
<td>88%</td>
<td>168</td>
<td>81%</td>
</tr>
<tr>
<td>Outgoing Sub, Mod (PEA 90 &lt; days requested)</td>
<td>80%</td>
<td>90%</td>
<td>438</td>
<td>98%</td>
</tr>
<tr>
<td>Closeout</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSR, Federal (submitted on time)</td>
<td>100%</td>
<td>100%</td>
<td>208</td>
<td>100%</td>
</tr>
<tr>
<td>FSR, Non-Federal (submitted on time)</td>
<td>90%</td>
<td>86%</td>
<td>136</td>
<td>88%</td>
</tr>
<tr>
<td>Final Invoices Submitted on Time</td>
<td>100%</td>
<td>98%</td>
<td>549</td>
<td>99%</td>
</tr>
</tbody>
</table>


Draft process maps are now available for the following business areas: RM Grants & Contracts and Finance Teams, the Partners Human Research Office (IRB) and the Partners Clinical Research Office (PCRO).

Updates to the draft process maps will be made upon implementation of additional reporting capabilities targeted for release in FY12 as well as upon input from Investigators and hospital administrators. PHS RM invites the research community to review these draft process maps and offer feedback at: researchfeedback@partners.org.

Process Maps Promote Transparency and Accountability

Given the large number of specialized and complex tasks required to manage all components of a sponsored award, it is critical to understand the different research support groups that exist and the various functions the individual teams perform. Process maps in draft format have been developed to clearly delineate the roles and responsibilities within the research offices as well as within the Hospitals that these offices support. This level of transparency is essential in ensuring compliance and timely processing of research related transactions. Additionally, the maps promote accountability and clarity around the various research functions which will guarantee operational efficiency and sound administrative and financial oversight.

BWH & MGH Historical Deficit Cleanup

As part of the overall effort to improve oversight of the growing research portfolio, RM and hospital leaders across BWH and MGH focused on addressing the historical deficits for accounts that ended in FY10 and prior. The deficit cleanup initiative resulted in significant reductions across both institutions: 97% decrease at BWH and 61% decrease at MGH. Resolution of the remaining balances is anticipated in FY12.
In collaboration with Research Applications and Hospital representatives, RM successfully implemented InfoEd Proposal Development (PD) to 100% of the 77 departments across BWH and MGH (136 different Chief Codes). This electronic routing system streamlines the proposal development process, eliminates administrative redundancies, allows for online review and approval and turnaround time reporting. It is a critical step in improving the proposal submission process and rolling out InfoEd System-to-System (S2S) submissions directly to NIH.

The implementation of the electronic effort certification process has lessened the administrative burden and greatly increased compliance with effort certification as required by federal agencies. The first two cycles have 100% completion rate. The most recent cycle is on track for 100% completion.

Complementing this new InfoEd PD capability, RM also worked with counterparts in the Office of Industry Interactions (OII) and Research Applications to effectively roll out an electronic Conflict of Interest Disclosure (eCOI) system for research proposals. The goal is to transition the collection of more than 30,000 paper-based, hard copy COI forms with an eForm alternative. This new mechanism saves time and costs while increasing accuracy and compliance. Since go-live in July, 4,535 eCOI’s have been completed for new proposal submissions. Additionally, in October 2011, a pilot was conducted to collect COI information for all existing research projects. To date a total of 3,268 forms have been submitted electronically as part of the Annual Research COI (ARC) pilot. Further improvements will be made to the COI process in FY12.

**InfoEd FY12 Focus**

- System-to-System (S2S) Pilot
- PD for SRH, McLean & PCRO
- PD for Internal Funding

**Conflict of Interest**

A total of 7,803 COI forms have been completed electronically. FY12 goal to transition 100% from paper collection.

**Electronic Conflict of Interest Disclosure (eCOI)**

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**Electronic Effort Certification**

The implementation of the electronic effort certification process has lessened the administrative burden and greatly increased compliance with effort certification as required by federal agencies. The first two cycles have 100% completion rate. The most recent cycle is on track for 100% completion.

**# of Forms Submitted in FY11**

- MCL, 208, 5%
- SRH, 26, 1%
- MGH, 2275, 53%
- BWH, 1776, 41%
PHS RM Intranet Moves to an External Internet Site

Based on numerous requests and feedback from the research community, the PHS RM intranet was transitioned to an external facing internet site to better serve the needs of Investigators and support staff. Important and useful information, such as policies, standard operating procedures (SOPs), online tutorials, funding announcements and department assignments are available to researchers through any internet connection and browser, allowing for immediate and convenient access.

Insight Fund Statement Goes Live

A new fund statement reporting tool was rolled out to the research community in mid-January 2011. Found in the Agreements Module within Insight, this tool helps both hospital department employees and RM staff to more accurately and effectively monitor accounts and facilitates proactive fund management. Each active fund is assigned an alert level (red, yellow or green) based on spending activity which enables department employees and RM staff to quickly isolate funds that are either overspent or at risk. The new fund statement also identifies the individual(s) responsible for taking the first step to resolve the issue, promoting efficiency and transparency.

Automated Subcontract Invoice Review & Approval

Routing collaborator invoices for review and approval has been fully automated. This new InfoEd feature allows an invoice to be viewed online and tracks its real-time status. It also distinguishes between low and high risk invoices and requires DA’s and PI’s to respond only when there are issues with the invoice or if it is high-risk. Since go-live, approximately 6,500 invoices have been processed electronically.

Other System Enhancements

As described above, RM, in collaboration with other offices, enhanced its systems infrastructure and rolled out a number of tools, resources and management controls to promote efficiency, to facilitate education and transparency and to ensure compliance and data integrity throughout the award lifecycle. The following other upgrades and technology solutions were implemented:

1. Implemented Project Controls to prevent non-personal spending on expired funds
2. Rolled out PeopleSoft billing for Cores
3. Automated Journal Entry submission and implemented in-system quality control review
4. Enhanced PeopleSoft EDC workflow & views
5. Automated monthly close
6. Advance Account Requests via Insight

RM Internet Statistics

Total Visits: 174,195
Avg Visit Length: 10:40

Top Pages:
1. Forms, Tools & Resources: 14,254
2. Proposals: 9,975
3. Key Contacts: 6,858

Most Downloaded Documents
1. COI Form: 4,575
2. Proposal Coversheet: 3,456
3. Journal Entry 20 Line: 3,401

PeopleSoft FY12 Goals

- PeopleSoft 9.1 Upgrade
- PeopleSoft Milestone billing capabilities
- PeopleSoft Billing for external Core users
In FY10, RM and members from other Partners research offices, worked together to respond to the increasing frequency of Foundation Sponsors including problematic terms and conditions in their research agreements which resulted in lengthy negotiations, consumed legal resources, frustrated Investigators and jeopardized donor relations. In FY11, Research Management rolled out a new process based on recommendations from the process improvement team that aimed to reduce the turnaround time of processing Foundation Awards. The process involves initiating master agreements and implementing a risk assessment matrix to evaluate terms and conditions and to allow for expedited processing of low-risk awards. Initial findings indicate, on average, that those eligible for Expedited Review (ER) are processed 20 business days faster than those not eligible and 30 days faster than Agreements executed the previous year (historical). Even awards not eligible for expedited review were processed 12 days faster than the historical average.

There has been significant growth in subcontract activity at Partners over the past four years and FY11 followed suit with an 11% increase in volume. Specifically, collaborative work between Boston-area institutions has grown tremendously and being able to manage the subcontracting process efficiently is critical to facilitating such essential partnerships and easing Investigator burden. To better manage this process, RM met with institutional representatives from Harvard and Harvard Affiliates as well as members from other area institutions throughout FY11 to develop new ways to streamline the contracting process. Resulting from this endeavor, a simplified process utilizing unilateral agreements will be used to award No-Cost Extensions and Carryforward approvals across all Harvard Affiliates. This should reduce the turnaround time in administering these collaborations.

In addition, RM and the Harvard School of Public Health have begun a pilot to utilize unilateral agreements for all subcontract modifications, including renewal years, which will further streamline the subcontracting process. These are preliminary steps towards realizing a comprehensive approach to improving collaborations across local universities and hospitals and continued efficiencies resulting from this strategic partnership are anticipated in FY12.

**Impact of Process Improvement on Foundation Awards**

**Strategic Partnerships Streamline the Subcontracting Process**
**Partners Clinical Research Office (PCRO) Embarks on Improvement Initiative**

In FY11, PCRO received feedback from the research community and leadership that clinical trial initiation turnaround time needed to be improved. To better understand the reasons for these delays and how to improve, an assessment of its overall business process was conducted. The primary focus of the assessment was to identify opportunities to reduce overall clinical trial initiation turnaround time. The assessment focused on:

1. Current contracting, budgeting and Medicare coverage analysis processes
2. Staffing Levels
3. Use of technology to support the work performed
4. Comparison of PCRO’s performance against top performing peers

As a result of this assessment PCRO developed a process improvement initiative and a plan for implementation in FY12 that is focused on clinical trial contracting, budgeting and Medicare coverage analyses.

The FY12 PCRO process improvement initiative is intended to reduce overall turnaround time for industry sponsored clinical trial initiation.

1. Hire two additional staff members to assist with clinical trial contracting and budgeting
2. Provide ongoing training to PCRO staff
3. Implement a central mailbox system to receive incoming agreements and related documents while PCRO is in the process of implementing InfoEd PD
4. Develop a process map with explicit expectations for PCRO, investigators and sponsors throughout the contracting and budgeting process
5. Revise the MCA process

Regular updates to the research community regarding the PCRO improvement initiative and implementation plan will be provided, including presentations at BRISC at BWH, RADG at MGH, Partners Research Issues Forum and ROM.

**Human Subjects Research Quality Improvement (QI) Program**

The QI Program also offers a range of education to study sites. Study start-up activities include study binder consultations which assist the site in proper study documentation and address appropriate management of study data. Small group inservices can be scheduled to provide the study site with an opportunity to ask questions, discuss policies and address sitespecific issues relating to the conduct of research.

If the investigator plans to or is the holder of an investigational drug/device application from the FDA, the QI Program can provide education of the application process and responsibilities according to federal regulations, and provide regulatory review of the application documentation.

FY11 accomplishments include:

1. 90 Onsite Audits & 44 Educational Activities
2. Completion of QI System for Tracking Analysis and Reporting (QSTAR)
3. Initiation of QI Study Start up Project: work with new investigators to provide study start up education within first 3 months of IRB approval and educational onsite review before first IRB Continuing Review
4. IRB/QI collaborative education roundable series to MGH/BWH research staff
Institutional Review Board (IRB)

<table>
<thead>
<tr>
<th>Type of IRB Activity</th>
<th>FY2011 Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Protocol Submissions</td>
<td>2,236</td>
</tr>
<tr>
<td>Continuing Reviews</td>
<td>4,771</td>
</tr>
<tr>
<td>Amendments</td>
<td>13,407</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>103</td>
</tr>
<tr>
<td>Other Events</td>
<td>1,152</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>21,669</strong></td>
</tr>
</tbody>
</table>

eIRB Sponsor Form Enhancements

The Insight eIRB Sponsor/ Funding form has been updated to allow users to search and add the Insight Agreement record regarding funding support for the research to the eIRB application. Adding an Agreement creates a link between the Insight Protocol and Agreement records so that Research Management staff can easily access the IRB review status of the Protocol(s) supported by the Agreement. When the user selects an Insight Agreement record, the Agreement information automatically populates the Sponsor/Funding form on the eIRB application, reducing the need to enter redundant information and the need to upload a copy of the grant to the eIRB/Insight Attachments page of the Protocol record. As before, when there are multiple Agreements supporting the research, users must complete a separate Sponsor/Funding form for each Agreement. For those protocols with no funding, or no funding to BWH/MGH, there is the option to indicate that there is no funding or no Agreement record in Insight. Investigators are reminded that new sources of funding support (Agreements) for ongoing approved human research must be added to the Protocol by amendment. The release of funds for human research will be delayed if the IRB has not reviewed the application for funding to ensure that the research described in the funding application is entirely consistent with the IRB-approved Protocol.

Human Research Investigator Disclosure Forms

As of June 2011, the requirement for completion of Investigator Disclosure Forms has been extended to any member of the study staff responsible for the design, conduct, or reporting of the research. The eIRB forms for new protocols and study staff amendments now require the Principal Investigator to identify any study staff person who, in addition to the PI, Site Responsible PI, or Co-I, has responsibility for the design, conduct, or reporting of the research. The PI should consider whether the tasks delegated to members of the study staff working under the direction of the investigators include responsibility for the design, conduct or reporting of the research.

Clinical Trials Registration

As of 07/01/11, investigator-initiated clinical trials conducted by Partners investigators that meet FDA Amendments Act (FDAAA) clinical trials registration requirements must be registered on ClinicalTrials.gov prior to IRB approval. The Clinical Trials Registration section of the eIRB forms for new and continuing review submissions now ask investigators conducting investigator-initiated clinical trials to provide the ClinicalTrials.gov registration number (e.g., NCT00000419) and to sign the designation of responsible party letter acknowledging responsibility for clinical trial registration and, if applicable, results and adverse event on ClinicalTrials.gov at the end of the study.

PHS HRPP Receives AAHRPP Reaccreditation for BWH & MGH

The BWH/MGH Human Research Protection Program (HRPP) underwent a reaccreditation site visit by the Association for Accreditation of Human Research Protection Programs (AAHRPP) March 28-30, 2011. The AAHRPP site visitors reviewed policies and procedures and conducted group interviews of individuals who are part of the BWH/MGH Human Research Protection Program (HRPP). The BWH/MGH as part of Partners HealthCare HRPP was fully re-accredited by AAHRPP on September 9, 2011 for a period of 5 years.
RM Workforce Training & Professional Development

Research Management’s Training and Workforce Development team strives to meet the training needs of the entire research community at BWH, MGH, McLean and Spaulding. The team’s goal is to provide the knowledge required by Principal Investigators, Department Administrators and RM employees to facilitate the ongoing administrative and financial requirements of sponsored research projects within Partners. The team is also committed to the professional development of employees and provides hands-on activities and personal development exercises to further enhance the learning experience and ensure participant success on the job.

The variety of programs offered are tailored to meet the needs of participants and to effectively address the learning requirements of newcomers to the field as well as individuals seeking a content refresher. Such programs include a specialized new hire trainee program for RM staff (59 graduates to date) and a customized grant management training program for DA’s and PI’s (180+ attendees to date). Both programs incorporate the seven core courses offered in the RM Quarterly Trainings that are open to all of the research community.

Training Schedules and other resources are available on the Research Management Internet: http://resadmin.partners.org.

PI Toolkit & New Clinical Investigator Training Program

The Training & Workforce Development team has created a number of online transactional tutorials for PIs, department employees and RM staff. These online resources address topics discussed in instructor-led trainings and are available anytime for individuals looking to develop new skills or enhance existing ones. Specifically, the PI toolkit serves as a resource for PIs who are new to the Partners network and PIs who may be looking for specific information related to the lifecycle of a grant. The toolkit provides PIs with guidance regarding their responsibility as it pertains to each step of the lifecycle as well as links to policies, forms and other helpful information.

Similarly, the New Clinical Investigator Training Program is now offered online for ease of use and convenience. Available tutorials include: the Institutional Review Board, an Intro to the Partners Clinical Research Office, and the Quality Improvement (QI) Program.

All online tutorials are available at: http://resadmin.partners.org.

Organizational Development & Structure

In an attempt to strengthen and to develop RM’s organizational culture and operational alignment with the Partners Strategic Plan and Mission, the RM Leadership team conducted an internal needs analysis. Resulting from this collaboration, the team identified, developed and implemented new strategies and enhancements within six "core" organizational areas: Leadership, Finance Operations, Information Technology, Roles & Responsibilities, Customer Service and Organizational Culture. With the combined effort of staff participation and management oversight, each core area convened throughout FY11 and generated numerous improvements throughout the office.

In FY12, RM will further operationalize these areas of focus. Also, to better manage daily operations and to promote consistency within RM, with the goal of improving customer service and compliance, the Pre- and Post-Award teams were each reorganized under a single Director, and a Manager-level team was appointed to help with daily oversight and HR processing.

Quarterly Trainings

1. Intro to Pre-Award
2. Intro to Post-Award
3. Intro to Finance
4. Hospital Cost Principles & NIH Grants Policy Statement
5. RM Policies & Procedures
6. OMB Circular A-110
7. Subcontracting

Other Online Courses

1. Employee Data Changes
2. Journal Entries
3. Deliverable Reporting
4. Insight Fund Statement
5. SF 424 Overview
6. InfoEd Tutorial

Org Development

1. Lunch & Learn Series
2. Employee Satisfaction Survey
3. Revised Rewards & Recognition Program
4. Roles & Responsibilities Pilot
5. Management Training & Workshops
6. Monthly Communication Forum
As stewards of sponsored funds for the Partners entities, Research Management is committed to identifying and adhering to best practices in grants and contracts administration and upholding the highest standards of integrity and fiduciary responsibility. RM seeks to proactively address the administrative demands on investigators by providing exceptional customer service to our distinguished research community and collaborators in their pioneering efforts in science and medicine.

FY12 Goals & Initiatives

RM remains committed to providing the very best service to the Partners HealthCare research community, and, as Fiscal Year 2012 gets underway, RM will focus its attention on the following areas:

1. Scope ways to improve the “user experience” for the research community
2. Pilot electronic proposal submissions (system to system) w/ 4 departments
3. Rollout PeopleSoft 9.1 to improve research transactions
4. Improve management of research collaborations
5. Improve billing and AR management
6. Incorporate operational reporting for all RM teams into one system
7. Streamline PCRO operations to reduce clinical trial agreements turnaround time
8. Leverage technology to improve IRB efficiencies and reduce handoffs
9. Improve functionality for research transactions with RM Applications and Systems teams