Departmental Research Administrators Workgroup (DRAW)

March 20th, 2012
deMarneffe 132
Agenda

- Introductions
- Announcements/Updates
- RPDR *(Mariah Mitchell)*
- Residual Balance Transfer Requests in Insight *(Raquel Espinosa)*
- eIRB *(Christina Booth)*
- Q & A - *All*
Announcements

INSIGHT: Sub-Contract Encumbrances

- Department Administrators requested improvements to the Subcontract Management and Budget Projection functionality in INSIGHT.
  - The INSIGHT 3.0 release on 3/2/12 included changes for sub-contract encumbrances: Budget feed modified to allocate $25k per sub (rules for institution/dollar amounts apply) per project into IDC Account Code 992699.
Continuation Announcements

INSIGHT: Sub-Contract Encumbrances

- Sub - contract name was changed to display in the line detail under the sub - contract budget
- IDC Account Code was implemented on funds with a start date after 10/1/2009

● These changes will resolve the encumbrance problem and help the departments to better read/manage their budgets.

● Additionally the sub - contract invoicing process approval at RM will ensure that invoice expenses are split between the overhead and non - overhead bearing lines
This fund is a **Budget** based account.
The fund is currently classified as: Active and is in good standing.
Your total cost fund balance is **$371,507.00** (Direct costs plus indirect costs, if applicable). This balance does not include encumbrances.

### Financial Details

<table>
<thead>
<tr>
<th>Category/Account</th>
<th>Last GL Post: 1/31/2012</th>
<th>Last PO/AP Post: 3/31/2012</th>
<th>Current Balance</th>
<th>Encumbrance</th>
<th>Projected Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salaries &amp; Wages</strong></td>
<td>$159,965.00</td>
<td>$205,915.69</td>
<td>($45,950.69)</td>
<td>$65,229.57</td>
<td>$(114,550.28)</td>
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<tr>
<td><strong>Fringe Benefits</strong></td>
<td>$55,966.00</td>
<td>$69,037.89</td>
<td>($13,071.89)</td>
<td>$22,970.35</td>
<td>$(36,360.24)</td>
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<tr>
<td><strong>Consumable Supplies</strong></td>
<td>$2,865.00</td>
<td>$5,750.21</td>
<td>($3,085.21)</td>
<td>$1,388.53</td>
<td>$(4,433.71)</td>
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<td><strong>Travel</strong></td>
<td>$5,464.00</td>
<td>$4,514.33</td>
<td>$979.67</td>
<td>$0.00</td>
<td>$979.67</td>
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<tr>
<td><strong>Non_Capital_Equip</strong></td>
<td>$0.00</td>
<td>$155.69</td>
<td>($155.69)</td>
<td>$0.00</td>
<td>($155.69)</td>
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<tr>
<td><strong>Other Expenses</strong></td>
<td>$295,404.00</td>
<td>$54,099.34</td>
<td>$241,304.66</td>
<td>$1,760.09</td>
<td>$239,544.66</td>
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<td><strong>Subcontracts</strong></td>
<td>$576,447.00</td>
<td>$524,968.35</td>
<td>$51,478.65</td>
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<td>92659 - Subk Exp subject to IDC</td>
<td>$75,000.00</td>
<td>$67,392.43</td>
<td>$7,607.57</td>
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<td>92701 - Mayo Clinic Rochester</td>
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<td>$0.00</td>
<td>$3,070.00</td>
<td>$3,070.00</td>
<td>$0.00</td>
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<tr>
<td>92702 - Broad Institute, Inc</td>
<td>$287,068.00</td>
<td>$261,044.75</td>
<td>$25,183.25</td>
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<tr>
<td>925715 - Harvard School of Public Health (HSPH)</td>
<td>$205,569.00</td>
<td>$195,532.16</td>
<td>$8,976.82</td>
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<td><strong>Total Direct Costs</strong></td>
<td><strong>$1,095,493.00</strong></td>
<td><strong>$867,403.81</strong></td>
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<td><strong>$143,060.05</strong></td>
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<tr>
<td><strong>Indirect Costs</strong></td>
<td><strong>$463,277.00</strong></td>
<td><strong>$319,759.68</strong></td>
<td><strong>$143,517.32</strong></td>
<td><strong>$77,482.08</strong></td>
<td><strong>$86,036.24</strong></td>
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<tr>
<td><strong>Total Costs</strong></td>
<td><strong>$1,558,770.00</strong></td>
<td><strong>$1,187,163.49</strong></td>
<td><strong>$371,606.51</strong></td>
<td><strong>$220,542.13</strong></td>
<td><strong>$150,819.37</strong></td>
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<tr>
<td>Total Revenue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>$1,187,163.49</strong></td>
</tr>
</tbody>
</table>

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**Partners Healthcare**

Founded by Brigham and Women's Hospital and Massachusetts General Hospital
Announcements

InfoEd PD Updates

- McLean is currently in the rollout phase and full implementation will be completed by the June NIH deadline.

- As of June 5th, 100% of all new research proposals sent to McL Research Administration will be required to be developed, reviewed, and approved within the InfoEd PD application (excluding RVL and PCRO proposals). As of that date, any new proposal submitted outside of InfoEd to McL Research Administration will not be accepted.
InfoEd PD Updates

- To help PIs and DAs learn how to use this new system, classroom training sessions were held on February 24th and March 2nd. Computer based trainings were offered on March 9th & 16th; there will be additional trainings offered depending on need. The goal is to have as many people as possible trained in the next month before the full roll-out.

- The link below provides information about documentation, an alternative training option and the PD Resource Center which is a discussion board for commonly asked questions related to using PD.

Research Patient Data Registry (RPDR) at Partners Healthcare

March 20, 2012
Objectives

- Overview of the RPDR
- Access and Authorization
- Summary
- Contacts and References
# RPDR Warehouse

Large warehouse of inpatient and outpatient data
- 5.0 million patients
- 175 million encounters
- 1.5 billion facts, coupled to demographics & visits
- 1.3 TB (30 TB)
- 115 thousand metadata concepts

### Data Sources:
- EMPI
- LMR
- OnCall
- PCIS
- BICS
- CDR
- TSI
- IDX
- SSDI
- CPM
- LMM/PowerPath

### Hospitals:
- MGH
- BWH
- NWH
- FH
- NSMC
- SRH
- McLean

### Concepts:
- Diagnoses
- Problems
- Medications
- Procedures
- Laboratory
- Health history
- Vital status
- Genomics
- Physical Findings

### Concept Code Sets:
- ICD-9
- LOINC
- CPT-4
- HCPCS
- NDC
- DSM-IV
- MEDITECH
- LMR
- Misys
- LMM
- Oncall
Use of the RPDR

- Research Patient Data Registry exists at Partners Healthcare to find patient cohorts for clinical research.

- There are two parts to the RPDR:
  1) Researchers obtain aggregate patient totals by using the online RPDR **Query Tool**.

  2) With proper IRB (Institutional Review Board) approval, researchers can obtain identified patient data using the **Detailed Data Wizard**.
Part 1 - Finding Patients

Query items

Person who is using tool

Query construction

Results - broken down by number distinct of patients
Finding Patients

[Image of the RPDR Enhanced Query Tool interface]

Query Name: Acute myocardial infarction, CK-MB Index (Gr. on 01/24/2011 #2)

Groups do not have to occur in the same visit.

Sensitivity: Reset all groups to NO > Specificity

Group 1 of 3
- One or more items recorded
- Acute myocardial infarction

Group 2 of 3
- CK-MB Index (Group CKMBRI) > 3.5

Group 3 of 3
- Drag items from the 'Query Items' and 'Find Items' Tab on the left into the group

Run Query
Total count: 21647±3 patient(s)

Gender
- Female: 13,906,83
- Male: 13,906,83
- Other: 13,906,83

Age
- 65: 46,53
- 66: 46,53
- 67: 46,53
- 68: 46,53
- 69: 46,53
- 70: 46,53

Race
- I: 46,85
- A: 46,85
- B: 46,85
- C: 46,85
- D: 46,85
- E: 46,85

Vital
- Alive: 46,85
- Deceased: 46,85

PARTNERS HEALTHCARE
FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL
Part 2 - Requesting Detailed Patient Data Sets

Methods for requesting detailed data about patients:

- The methods listed below allow you to gather detailed data about patients. Some of the methods depend upon a currently active query which is identified in the Aggregate Query group panels. You can drag a finished query from the "Previous Queries" panel on the left and drop it on the Aggregate Query group panels to activate the query. Please see the individual instructions for each method. When you press the "Start" button, a new internet browser window should open. If you have a popup blocker or similar software enabled, you may need to disable it to allow this program to function properly.

1. **Using a query** - Create a Detailed Data Request based upon an Active query

2. **Using a known list of MRNs** - Create a Detailed Data Request based upon your list of MRNs

3. **To obtain new MRNs periodically** - Create a scheduled request for an MRN list

**Wizards**
Identified data is gathered

Output files placed in special directory

Data is gathered from RPDR and other Partners sources

Files include a Microsoft Access Database
Value to McLean

- Feasibility studies, cohort identification
  - of this criteria (age, gender, inpatient, treatment dates)
  - on medication A, B (Lithium, Risperidone, Lexipro, Geodon, etc.)
  - with diagnosis of X (Depression, Schizophrenia, Anxiety Disorder, etc.)

- Recruitment for clinical studies
  - Pt data & demographics available through detail data request
  - Contact/PCP info available via EMPI services data

- Access to data across PHS (with IRB & site collaborators)
RPDR Access and Authorization

Users are granted authorization to the RPDR either as a faculty sponsor and leader, or a workgroup member.

- **Faculty Sponsor:** RPDR applicants who meet the following criteria may be added as Faculty Sponsors, and are authorized to use the RPDR Query Tool to query clinical data for aggregate numbers and must approve all team requests for data (all 3 of the following criteria must be fulfilled:)

  1. Harvard or Tufts faculty appointment or special designation by IRB and
  2. Clinical appointment to the professional staff at a Partners Healthcare System site (Affiliated Covered Entity) or in the case of PhD faculty, employed at a Partners Healthcare System site and
  3. Partners NT logon ID.

- **Workgroup Member:** If you are not a faculty member and wish to obtain RPDR access, you must be added by a faculty member to their workgroup.
Summary of RPDR features:

- Partners' patient database system designed for investigators, with HIPAA compliant access to data on millions of Partners patients
- User-friendly Query Tool for efficient, online access to complex query formation, including alphabetical lookup of query items
- Availability of query items such as diagnoses, laboratories, and demographics (see the RPDR Data Dictionary for a complete list of query items)
- Access to all Previous queries, and building upon prior queries.
- Automated, on-line Help, Tutorials and Faculty registration via web address: http://rpdr
- Identified patient data such as encounters, laboratories, operative notes, discharge summaries (see the RPDR Data Dictionary for a complete list of data items), is available to researchers in a secure Access database with IRB approval.
- **Security across all operational and technical phases of the system
- State-of art-technology with Partners IS support
References and Contacts

- RPDR Home page: [http://rpdr](http://rpdr)
- RPDRHelp@partners.org

Contacts:

Laurie Bogosian, Application Analyst
617-643-5896
lbogosian@Partners.org

Stacey Duey, Project Specialist
617-643-5283
sduey@partners.org

Mariah Mitchell, Team Lead
617-643-5883
mpmitcell@partners.org
Questions?

Thank you!
**Security and Patient Confidentiality of Part 1**

- All patients at Partners are added
  - HIPAA notification that their data may be used for research upon registration.

- RPDR data is anonymized at the Query Tool.
  - Aggregated numbers are obfuscated to prevent identification of individuals; automatic lock out occurs if pattern suggests identification of an individual is being attempted.

- Queries done in Query Tool available for review by RPDR team, a user lock out will specifically direct a review.

- De-identified data warehouse is a “Limited Data Set” by HIPAA
  - Medical record numbers are encrypted and obvious identifiers are removed from data.

- Concept of “established medical investigator” is promoted by classification as a faculty sponsor.
**Security and Patient Confidentiality of Part 2**

- Only studies approved by the Institutional Review Board (IRB) are allowed to receive identified data.

- Queries may be set up by workgroup member, but faculty sponsor on IRB protocol must directly approve all queries that return identified data.

- Special controls exist when distributing data regarding HIV antibody and antigen test results, substance abuse rehab programs, and genetic data, due to specific state and federal laws.

- Queries that return identified data are reviewed (retrospectively) by the IRB.
Residual Balance Transfer Requests

- RBT module in Insight went live and all requests can be submitted and processed electronically.
- Since 2009 Audit McL Hospital is required to use the institutional RBT request form in addition to Partners RBT request.

STEPS TO SUBMIT AN RBT:
1. Email Research Administration the McL RBT Checklist
2. Submit RBT in Insight

Workflow:
- After PI signs off on the RBT request, Research Administration will be sent an email alerting to review the request. If questionable, we will work with you on needed changes.
RBT continuation

- Grant Administrator
- PI
- Institutional Research Administrator at MCL (upon receipt of McL RBT request form)
- Dept Chief (only if there is a significant balance)
- VP of Research (only if there is a significant balance AND the Dept Chief is also the PI on the fund)
- Research Finance Contact (for deficit review)
- Finance Sign off (Rick Mancinelli or Anna Rayz)

The “From” Fund must be a fund code 72 (non-federal clinical trial)

The “To” Fund must be a fund code 66 (a research sundry)

A significant balance is defined as a balance of greater than 20% of the revenue and/or greater than $100,000

The “Eligible for Transfer to Research Sundry” amount is calculated by Insight using a formula that factors in the cash balance and the IDC rates of the two funds.

- Amount to transfer = Cash balance\text{A} – (\$\text{IDC A}-\$\text{IDC B})
- If fund\text{A} has 0% IDC, amount to transfer = cash balance
- If fund\text{B} has higher IDC rate than fund\text{A}, amount to transfer=cash balance
Human Research Protection Program

e-IRB Implementation Plan

Christina Booth MS HPM, CIPP
Administrative Chair
Mclean Hospital
Human Research Protection Program
March 20, 2012
Overview

- Timeline for Implementation Electronic Application Submission via e-IRB
- Training Resources
- Issues for Investigators Ceded Reviews, Multiple Sites, CT.gov
- Application Processing Times: Expectations
What will go live?

- Relational database using the Insight platform
- First IRB component implemented at McLean will be electronic application submissions

What Types of Applications:
- New Studies (Exempt, Expedited and Full Board) and all attachments
- Continuing Reviews
- Amendments
- Adverse Events
- Other Events
- Exceptions
Time Line

**e-IRB**

- **IRB**
  - Initial Training
  - Online Application Submission

- **Meeting Management Functions in Development Through July**

- **Testing Through October Implementation October-December**

** Intro to e-IRB Training Sessions

** Cutover Date: Only e-IRB Submission

** HRPP will accept e-applications after attending an introductory

** Specialized IRB Sessions

- March
- April
- May
- June
- July
- Aug
- Sept

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Training Sessions

- Introduction to Application Submissions
  - March 23
  - April 6
  - May 3
  - RSVP ccostello@partners.org

Specific Training: Will be Scheduled and Announced in April

PIs and Staff must attend the session before we will accept e-IRB applications

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>March 23, 2012</strong></td>
<td>Howard Room, Administration Building</td>
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<tr>
<td>10:00-11:30 AM</td>
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<tr>
<td><strong>April 6, 2012</strong></td>
<td>Pierce Hall, Administration Building</td>
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<td>12:00-1:30 PM</td>
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<td><strong>May 3, 2012</strong></td>
<td>Putnam Room, Administration Building</td>
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<tr>
<td>2:00-3:30 PM</td>
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</table>
Training Resources

- Online Resources
  - e-IRB Overview
  - General Information about Insight and Research Management Internet
  - User Manual
  - Electronic Application Forms
  - Frequently Asked Questions

- Health Stream will have Introductory Session later in the year

- e-IRB Helpdesk
Sticky Issues

- Sign offs and Approvals
- Ceded Reviews
  - Harvard Catalyst
  - Other Institutions via IAA
- Multiple Research Sites (encourage IAA)
- Guest Investigators
Researchers **must register at CT.gov first to get an NCT number**

- The NCT number is required in order to submit an application via e-IRB
- Applicable Clinical Trial
  [http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm?q2=a+drug+or+biologic](http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm?q2=a+drug+or+biologic)


- ICJME Registration is **not** a condition of e-IRB submission
- All trials that began after July 1, 2005 should register immediately
- Ongoing trials started before July 1, 2005 and are ongoing
### Turnaround Time

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Estimated Protocol Review Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>(If no changes are required)</em></td>
</tr>
</tbody>
</table>

#### Research Determination or Exemption, Exceptions, Other Events
- 1 Week
- IRB Office reviews these inquiries upon receipt and notification follows according to level of urgency

#### Expedited
- Up to 4 weeks

#### Full Board
- Please see IRB Meeting Schedule
- 4-8 weeks

#### Amendments
- Minor Changes: 1 Week
  - This only includes a few changes (1 or 2 staff updates or correction of typographical errors): 1 Week
  - Changes that require analysis of multiple protocol documents or changes to the population being studies, the purpose of the study, or procedures will require longer review times: Often the original level of review the protocol (expedited or full board) will be required and those times will apply
Thank You

- e-IRB Application Submissions will be implemented over the next 4 months. Cutover date will be July 15, 2012: After this date no other type of submission will be accepted.

- Training Resources online and live:
  - No Training = No Electronic Submission
  - Ceded Reviews, Multiple Sites, CT.gov

- Processing Times will increase initially, the board and administration will be learning and implementing new components of the e-IRB system over the next year

- Questions?
  - irb@mclean.harvard.edu
Questions?
Contact

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respinosa@partners.org
respinosa@mclean.harvard.edu
respinosa@mclean.harvard.edu