Agenda

- Introductions
- Announcements (R. Espinosa)
  1) Journal Entries Training
  2) Transfers of Cash
  3) PO and EDI process
  4) Time off with pay (TOWP)
  5) McL Research Finance Coordinator
- Research Management Draft Policies (R. Espinosa)
- Partners Institutional Biosafety Committee (T. Myatt)
- Transferring Roles & Responsibilities to Partners (P. Paskevich)
- Email Migration to Partners Exchange (P. Paskevich & N. Yale)
- Open Forum: All
Announcements

1) **Journal Entries Training**
Courses will be soon announced by Partners RM – stay tuned!

2) **Transfer of Cash Requests**
   - Research Administration submits all transfers to Research Finance along with requests to write off and closeout funds
Continuation Announcements

3) Purchase Orders and EDI Vendors
   - Polly Burke transferred to a different role and is no longer the contact for closing out PO’s and for adjusting encumbrances.
   - Until further notice, please direct Materials Management questions and issues as follows:
     - For purchase order closeouts, submit requests to the PHS Research PO mailbox at ResearchPO@partners.org.
     - For Project Controls inquiries, please contact Angie Cheng at ascheng@partners.org
Continuation Announcements

4) Time off with pay (TOWP)

Many McL employees appear to use TOWP interchangeably with vacation, or they have a legitimate reason for use of TOWP but do not comply with policy and do not contact Occupational Health

• if employee is absent 3 days or less - manager's call
• if unable to work for 5 or more consecutive days – doctor’s note and Occupational Health needs to be involved

For more information, please see the TOWP Policy:
http://mclean.partners.org/policies/hrPoliciesLinkedDocs/TOWP%20Policy.pdf
Continuation Announcements

5) McL Research Finance Coordinator

- Please join us in wishing Mike Roberts well! After 13 months in the position he decided to start a writing career in NY.
- Research Management is working on recruiting this position
- In the meantime, please contact: Raquel Espinosa: Post-award matters
  Angie Cheng: Finance matters
Research Management Draft Policies

Departments are the best source to assess whether process is working or needs refinement!

1) Complex Award Management:
http://resadmin.partners.org/RM_Home/Documents/SOPs/SOP-PPG.pdf

Purpose:
Ensure there will be a dedicated administrator to manage award and fund is set-up correctly
Comments were originally due in August but RM is still receiving feedback

2) New Policy on Internal Consulting on Research Grants and Contracts:

Purpose:
Encourage collaboration in the system while being in compliance
Comments were due 09/19 – Research Administration provided feedback
Partners Institutional Biosafety Committee

Ted Myatt, Sc.D.
Director, Partners IBC

McLean DRAW
September 20, 2011
Agenda

• Overview of NIH Grant Policy Statement, NIH Guidelines and other regulations

• Definitions

• Upcoming changes to review procedures at Partners
Policy Debate

- NAS Committee Report (1974); called for:
  - A moratorium on certain experiments
  - Development of NIH guidelines for conduct and review of rDNA experiments,
  - An international conference
Asilomar Scientific Summit (1975)

- Premise:
  - Scientists taking responsibility for the risks of their own research activities

- Outcomes:
  - Reaffirmation of the need for guidelines
  - Establishment of a new federal oversight committee
NIH Guidelines

• **NIH Guidelines for Research Involving Recombinant DNA Molecules**
  – Published in 1976, updated most recently in May 2011
  – Under purview of the NIH Office of Biotechnology Activities (OBA)
  – Covers all rDNA research at NIH funded institutions, regardless of funding for individual grant funding source.

• Establishes requirement for and responsibilities of **Institutional Biosafety Committee (IBC)**
  – IBCs cover review and approval of preclinical and clinical use of rDNA
  – Requires IBCs to register with NIH OBA and submit annual report of activities

• Referenced as a term and condition of NIH funding in the NIH Grants Policy Statement
  – “Failure to comply with these requirements may result in suspension or termination of an award for recombinant DNA research at the organization, or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization.”
ICB Responsibilities

• Peer-review committee
  – Review and approval of preclinical and clinical use of rDNA prior to use by investigators
  – Required to include community members that represent the interest of the surrounding community with respect to health and protection of the environment

• Review is focused on safety of staff, public and environment

• Most IBCs have expanded focus beyond rDNA to also review infectious agent research
Definitions

• **Recombinant DNA (rDNA)**
  - Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or molecules that result from the replication of those described above.
Definitions

• **Viral Vector**
  – Tool used to deliver genetic material into cells
    • For example, to determine the effect of a specific gene, viral vectors can be used to “turn on” (upregulate) or “turn off” (silence) the gene.
  
• Used for *in vitro* and *in vivo* studies

• **Safety Concerns:**
  – Pathogenicity of parental virus
  – Cytopathogenicity of vector
  – Unknown or unanticipated outcomes
Institutional Responsibilities

1. Establish an Institutional Biosafety Committee (IBC).
   - At least 5 members w/expertise in rDNA; no limit on the maximum membership.
   - At least 2 members not affiliated w/institution.

2. Appoint a biosafety officer and animal containment expert.

3. Assist and ensure compliance with the NIH Guidelines by PIs conducting research at the institution.

4. Ensure training for the IBC members, biosafety officer and other containment experts, PIs, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines.

4. Determine the necessity for health surveillance of personnel involved in connection with rDNA projects.

5. Report any significant problems, violations or significant research-related accidents or illnesses to NIH within 30 days.
eIBC Research Review Process

PI
- Submits research (initial, amendments, annual updates) details via eIBC
- Conducts initial risk assessment
- Identifies appropriate NIH Guideline citation

BSO
- Reviews for completeness / assists PIs
- Assesses risks / recommends safety conditions
- Confirms NIH Guideline citation

PIBC
- Reviews research
- Ensures research meets regulatory requirements
- Approves research with appropriate safety conditions

Partners Institutional Biosafety Committee (PIBC) | 617-732-8330 | PIBC@partners.org
Principal Investigator Responsibilities

The Guidelines articulate a number of responsibilities for the PI including:

1. Proficiency in good microbiological techniques.
2. Instruct and supervise laboratory staff.
3. Determine whether their research is subject to the NIH Guidelines.
4. Submit information to IBC for review; obtain approval before initiating research, submit subsequent changes to IBC.
5. Propose appropriate containment levels and microbiological techniques in accordance with NIH Guidelines and a risk assessment.
6. Seek NIH approval for certain types of research.
7. Report any significant research-related accidents or illnesses to IBC.
Other Relevant Regulations

• Federal:
  – Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard

• State
  – The MDPH Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII)

• Local
  – The BPHC Recombinant DNA Technology: Use Regulations, BPHC Disease Surveillance and Reporting Regulation, and the BPHC Biological Laboratory Regulation
    • [http://www.bphc.org/programs/cib/environmentalhealth/biologicalsafety/Pages/Home.aspx](http://www.bphc.org/programs/cib/environmentalhealth/biologicalsafety/Pages/Home.aspx)
  – The CPHD Biosafety Regulation
    • [http://www.cambridgepublichealth.org/services/regulatory-activities/biosafety/overview.php](http://www.cambridgepublichealth.org/services/regulatory-activities/biosafety/overview.php)
  – The Town of Belmont Regulation for the Use of Recombinant DNA Molecule Technology and Non-Recombinant Infectious Agents
    • [http://www.mhoa.com/belmont.htm](http://www.mhoa.com/belmont.htm)
Current Status of Partners Biological Research

• Research currently reviewed by HMS Committee on Microbiological Safety (COMS)

• 988 active approved COMS registrations at MGH, BWH, and McLean
  – 62% involve rDNA / subject to the NIH Guidelines
  – 48% involve use of laboratory animals
  – 3% involve clinical trials (human gene therapy, rDNA vaccines, or infectious agents)
  – 1% involve use of Biosafety Level 3 organisms (M. tb)

• Annual approvals have increased by over 50% from 2005 to 2010
Upcoming Changes – Nov. 1 2011

• PHS institutions are leaving COMS and forming a new IBC – **Partners IBC (PIBC)**

• Development of **Insight eIBC** online submission module
  – Linkage to PeopleSoft, eIRB, eIACUC, Grants/Contracts
  – Arranged for data transfer from COMS database to eIBC (No need to re-submit or review COMS approved research)
  – Ability to add “Administrator” to registrations
Migrating from COMS to PIBC on November 1

What does that mean for investigators?

• Last COMS meeting that will review registrations is **Oct 28**.
  – Deadline to submit for this meeting is **Oct 1**.

• Starting **Nov 1**, investigators must use the new eIBC module to submit registrations to the PIBC

• First PIBC meeting is scheduled for **Dec. 7** (will meet monthly)
- eIBC will be coordinated with eIRB to avoid duplication and redundant data entry
- Incorporates ESCRO forms
Currently Developing eIBC Module

• Easy to understand forms that minimize effort to complete

• Workflows for clinical trial and laboratory research

• eIACUC and eIRB coordination to avoid investigator duplication

• ESCRO forms added into eIBC

• Existing COMS approvals and contact information migrated into eIBC
eIBC Training

- Training courses on eIBC will begin in October. Schedule will be announced soon.

- Starting in November, we will have scheduled “office hours”

- Laboratory, Department, or small group trainings can be scheduled now. Call or email me.
• Developed and launched PIBC Website
  – Located on RM internet site under “Research Oversight Committees” tab
Biosafety Contact Information

• MGH and McLean
  – Anne Sallee, Biosafety Officer
    • Phone: 617-724-4579
    • asallee@partners.org
    • http://intranet.massgeneral.org/ehs/ehs_home.htm

• BWH
  – Jessica Healey, Biosafety Officer
    • Phone: 800-825-5343
    • jhealey1@partners.org
    • http://bwhbri.partners.org/BWH_EnviroAffairs/default.asp
Questions?

Please contact me:

Ted Myatt, Sc.D.
tmyatt@partners.org
617-732-8330

PIBC Website
  - Located on RM internet site under “Research Oversight Committees” tab
Case Study 1

• Researchers receive shipment of Live Vaccine Strain (LVS) of *Francisella tularensis*, the organism that causes tularemia from a collaborator in another state.
  – *F. tularensis* normally requires BL3 containment, but the LVS strain can be worked with safely at BL2.
  – The IBC reviews and approves the work at BL2 and the work commences.
Case Study 1

• 3 staff become ill
  – LVS stock contaminated with wild-type, virulent form of the organism.
  – Institution delayed reporting infectious to appropriate agencies

• Institution should have required that shipment was tested for wild-type organism
Case Study 2

• Laboratory is conducting an IBC approved project in which *Brucella*
  – Brucellosis causing flu-like symptoms such as fever and fatigue. But in severe cases, it can cause infections of the central nervous system.

• Staff is short staffed and asks for help from staff from another lab
Case Study 2

• Lab worker is not trained to use *Brucella* and becomes infected when cleaning aerosolization chamber

• CDC finds a number of violations
  – Lab not authorized to aerosolize Brucella, did not have appropriate SOPs

• Institution should have verified training and SOPs

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*February 21, 2008*

**Texas A&M to Pay $1-Million Fine for Biosafety Violations**

*By Jeffrey Brainard*

In its research on dangerous microbes that could be used for biological warfare, Texas A&M University at College Station did not play by the federal safety rule book. Now it will pay the price—a fine of $1-million, the university announced on Wednesday. The institution hopes this will be a first step toward resuming the research, which the government suspended last summer, as early as March.

The university’s new president, Elsa A. Murano, only six weeks on the job, indicated
McLean Hospital Research Administration Process Improvement ("The Project Plan")
Research Administration Project Management

• **McLean Steering Committee**
  – Responsibilities – meet every other week (or more if necessary) to:
    • Assign tasks and initiatives
    • Monitor plan implementation / progress
    • Identify obstacles and potential problems; develop plans to appropriately respond
    • Ensure appropriate resources and prioritization
    • Provide updates to S. Rauch and P. Markell

  – Members
    • Peter Paskevich, Chair (Sr. VP for Research Administration)
    • Raquel Espinosa (Associate Director, Research Administration)
    • David Lagasse (CFO)
    • Catharyn Gildesgame (Director, Strategic Implementation)

  – Administrative Support
    • Kim Paulk (Administrative Manager)
Project Plan Objectives

- Clarify and differentiate roles and responsibilities of McLean PIs, PHS Research Management (RM), McL Research Administration (McL RA) and other key supporting offices

- Evaluate re-assignment of roles to PHS RM to take advantage of centralized expertise and economies of scale

- Ensure PI’s have appropriate level of support inside/outside their departments
Transferring Roles & Responsibilities

Re-assignment of roles to PHS Research Management to take advantage of centralized expertise and economies of scale

Transfer of Functions

PCRO (Partners Clinical Research Office)

Industry-sponsored clinical research

*Tasks:* Drafting and negotiating agreements and budgets; preparing Medicare Coverage Analysis (MCA) when required. *Projected Volume:* 10-15 studies/year

RVL (Research Ventures & Licensing)

Industry-sponsored pre-clinical research

*Tasks:* Reviewing and negotiating agreements

*Projected Volume:* 5 - 10/year

RVL (Research Ventures & Licensing)

*Tasks:* Intellectual Property Protection, Technology Transfer, MTAs, CDAs, invoicing, tracking and distributing milestone and royalty payments.

*Projected Volume:* 10 new disclosures /year

G&C (Grants & Contracts)

*Tasks:* Complex Subcontracts

*Projected Volume:* 10 /year
Why this is important and how it will benefit you

• Increased efficiency by leveraging PHS Research Management centralized expertise and economies of scale

• Improved customer service and efficiency by consolidating functions in specialized offices

• Increased accountability through clarification of roles and responsibilities, reporting relationships

• Increased support for PIs provided by knowledgeable, effective and efficient key contacts per activity

• Competitive budget negotiations with industry sponsors

• Licensing and Marketing of inventions
# Research Metrics

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<th>Division Name</th>
<th>Number of New Federal Awards FY11 YTD</th>
<th>Total Award</th>
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<tr>
<td>Alcohol &amp; Drug Abuse Division, Director: Roger Weiss, MD</td>
<td>3</td>
<td>$1,168,851</td>
</tr>
<tr>
<td>Basic Neuroscience Division, Director: Joseph Coyle, MD</td>
<td>6</td>
<td>$4,490,580</td>
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<tr>
<td>Neuroimaging Center, Directors: Scott Lukas, PhD &amp; Diego A. Pizzagalli, PhD</td>
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<td>Psychotic Disorders Division, Director: Dost Ongur, MD, PhD</td>
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<td>Divisions to be Established</td>
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<tr>
<td>TOTALS</td>
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<td>$7,609,019</td>
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Email Migration to Partners Exchange

Timeline
Right now this is TBD, currently we will assess weekly and provide a 4 week buffer for "transition".
Benefits of Migrating to Partners Exchange

- Access to the Partners Global Address book—all users across PHS in exchange, auto lookup
- Shared Calendar functionality
- Integrated Calendar, email, notes, tasks, etc;
- Email access outside the hospital via robust website
- Integration with smart phones (blackberry, iPhone/iPad)
- Ability to delegate to administrative managers
- Out of office messages to both internal and external recipients
- 24x7x365 support
- Continue with @mclean.harvard.edu, also receive mail via partners.org, mclean.org. Ability to set any of these as primary send/receive.
What Researchers Have To Do

- On the "Go-Live" or "Transition" day the researchers will have to configure their new or existing partners accounts in their email clients in order to send and receive new email. The researchers will also have to transfer their mail out of their existing McLean Email account before McLean Email server gets shutdown (Exact Date TBD).
- McLean RIS/ERIS is on site and ready to assist the Researchers if they need help configuring their email clients, folders, etc.
- Documentation has been developed to also assist them with this step and has been posted to the RIS site.

Storage Space

100 or 300 to start, depending upon current size. Larger mailboxes through a process that is currently being developed that may come with a charge per larger mailbox.
Questions?
Contact

Raquel Espinosa
Phone: 617-855-2868
respinosa@partners.org